COMPARISON OF EFFICACY OF DIFFERENT CONCENTRATION OF BUPIVACAINE IN ULTRASOUND-GUIDED TRANSVERSUS ABDOMINIS PLANE(TAP)BLOCK FOR POSTOPERATIVE PAIN RELIEF IN LOWER SEGMENT CESAREAN SECTION

Dissertation submitted

In partial fulfillment for the award of

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CERTIFICATE

This is to certify that this dissertation titled "COMPARISON OF EFFICACY OF DIFFERENT CONCENTRATION OF BUPIVACAINE IN ULTRASOUND-GUIDED TRANSVERSUS ABDOMINIS PLANE(TAP) BLOCK FOR POSTOPERATIVE PAIN RELIEF IN LOWER SEGMENT CESAREAN SECTION" has been prepared by Dr. P.D.Subha under my supervision in the Department of Anesthesiology, Government Kilpauk Medical College, Chennai during the academic period 2010-2013 and is being submitted to the Tamil Nadu Dr.MGR Medical University, Chennai -32 in partial fulfillment of the University regulation for the award of Degree of Doctor of Medicine (M.D Anesthesiology) and her dissertation is a bonafide work.

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DECLARATION

I Dr. P.D.Subha, solemnly declare that the dissertation , "COMPARISON OF EFFICACY OF DIFFERENT CONCENTRATION OF BUPIVACAINE IN ULTRASOUND-GUIDED TRANSVERSUS ABDOMINIS PLANE(TAP)BLOCK FOR POSTOPERATIVE PAIN RELIEF IN LOWER SEGMENT CESAREAN SECTION" is a bonafide work done by me in the Department of Anaesthesiology and Critical care, Government Kilpauk Medical College, Chennai under the guidance of Prof. Dr.S. Gunasekaran, M.D. D.A.,D.N.B., Professor and HOD, Department of Anaesthesiology, Government Kilpauk Medical College, Chennai.

Place: Chennai Signature

Date: (P.D.Subha)

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CONTENTS

1. INTRODUCTION

Women undergoing cesarean delivery present distinctive set of challenges to the anaesthesiologist in the immediate postoperative period . These women want to be active in the postoperative period to care their child. The American college of obstetrics & gynecology states that the objective of postoperative analgesia in cesarean section patients is to hasten early ambulation, postoperative recovery and promote maternal infant bonding [1].

Various modalities of treatment are available for controlling postoperative pain effectively like usage of opioids/NSAIDS, regional techniques and field blocks. As a part of postoperative analgesic regimen, initially opioids are required for effectual analgesia. But opioids can cause side-effects like emesis, nausea, itching, sedation, and respiratory depression [2]. Hence alternative regimen that reduces opioid requirements will be beneficial in this population [3]

Post-cesarean section pain and discomfort may be anticipated due to skin incision, uterine incision and uterine contraction. A significant amount of pain the patients feel is due the surgical incision. Hence blocking sensory nerve supply of the anterior abdominal wall will provide effective postoperative analgesia.TAP block is one of the regional anaesthetic techniques that block the innervation of abdominal wall.

McDonnell and his colleagues demonstrated the effectiveness of transversus abdominis plane (TAP) block for postoperative analgesia in cesarean section patients. He performed TAP block with 1.5 mg/kg ropivacaine and demonstrated reduced postoperative visual analog scale pain scores . It has been very well proved by various studies that TAP block is a promising approach in providing good postoperative analgesia.

Mcmorrow and his collegues in their study used 1mg/kg of 0.375% bupivacaine in landmark based approach of TAP and showed its effectiveness.

Especially use of ultrasound for TAP block, provides real time images that can be seen during the procedure and drugs can be given more exactly into the desired location than performing a blind technique to block the nerves. This technique increases the safety of the procedure[4].

In a study done by Hyun jung shin and his colleagues, in patients undergoing gynecological surgeries, they used 0.375% ropivacaine in TAP block under ultrasound guidance and concluded that US-TAP block has decreases narcotic use and improves the patient satisfaction .

Costello and colleagues used 20 ml of 0.375% ropivacaine bilaterally in TAP under ultrasound guidance and demonstrated its opioid sparing effects in postoperative analgesic regimen.

Baaj and his colleagues used 40 ml of 0.25% bupivacaine in ultrasound guided TAP block and proved its effectiveness.[19]

Though there are many clinical trials using various local anaesthetics in different concentrations in TAP block, there is no standard guidelines regarding the choice of local anaesthetics, its dose and concentration to be used. Since there have been no published dose-response studies investigating the effective analgesic dose of bupivacaine for use in a TAP block for postoperative analgesia, we proposed a study primarily examining the effect on requirement of first dose of rescue analgesia when 0.25% bupivacaine, and 0.375% bupivacaine are used for TAP blocks. Hence the goal of our study is to compare the effectiveness of 0.25%Bupivacaine and 0.375% Bupivacaine in ultrasound-guided TAP (Transversus Abdominis Plane) and the intensity of blockade provided by them as a part of postoperative analgesic regimen in patients undergoing lower segment cesarean section via pfannensteil incision.

2. HISTORY OF TAP BLOCK

This block was enumerated by Rafi in 2001[5]. He described it as a advanced regional block, in which local anesthetics can be delivered into the TAP in a single shot. This was a noteworthy advance from previous techniques in which multiple injections into the anterior abdominal wall, which was called as abdominal field block [6].

In 2004, McDonnell et al. in his works, provided evidence for the anatomical basis of TAP blocks with his publications. He demonstrated the sensory loss in the abdominal area after local anesthetic injection in the transversus abdominis plane.

In 2007, McDonnell termed the technique as TAP block and evaluated its effectiveness in patients who underwent prostate surgery [8].

In 2007, Hebbard in his randomized control studies demonstrated the ultrasound guided TAP block and its superiority over blind TAP procedure.[15]

In 2011, Niraj et al, in his randomized controlled trials found that the analgesic efficacy of epidural opioids are comparable with that of TAP block[16]

There are few clinical trials supporting the usage of catheters in TAP plane for continuous infusion of drugs, as a part of analgesic regimen

As this regional technique is a recently developed and promising modality for providing efficient post operative analgesia, many clinical trials are under progress to find its use in various types of surgeries.

3. ANATOMY OF ANTERIOR ABDOMINAL WALL

The abdomen has three muscle layers in its wall namely, the external oblique muscle, the internal oblique muscle, and the transversus abdominis muscle. The central part also has the rectus abdominis muscle and the associated fascial sheath.

3.1 DERMATOMAL SUPPLY OF ANTERIOR ABDOMINAL WALL

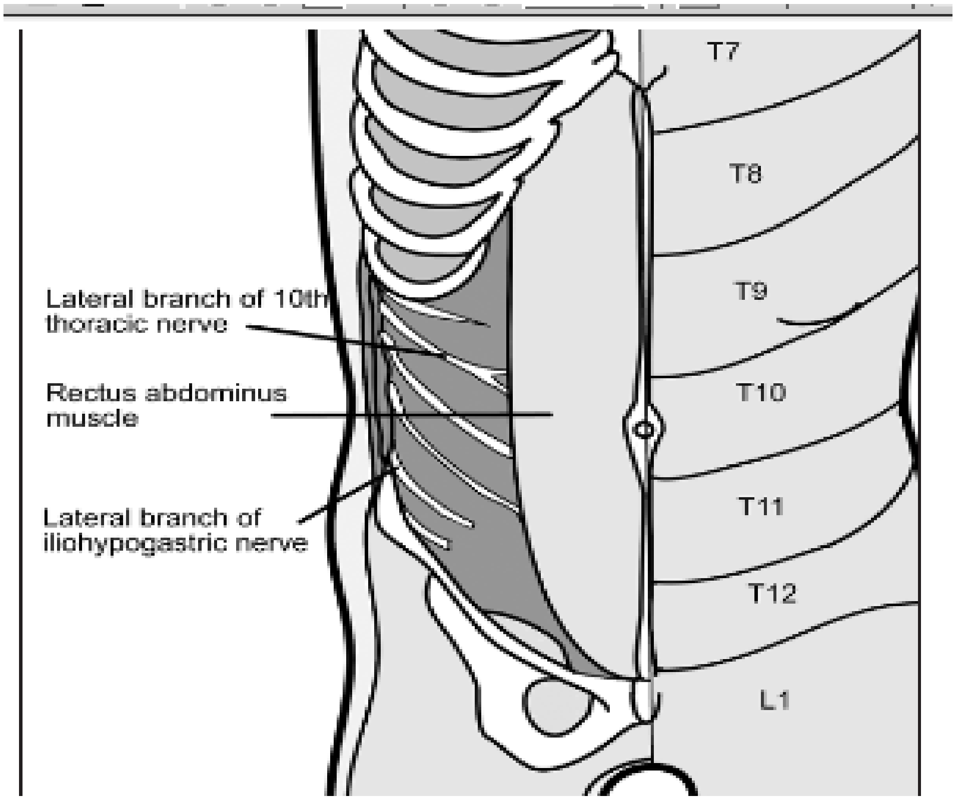
The T7 to L1, innervates the anterolateral part of the abdominal wall. The innervating spinal nerves are the intercostal nerves (T7-T11), the subcostal nerve (T12), and the illiohypogastric and illioinguinal nerves (L1. The anterior divisions of the intercostal nerves (T7-T11) emerges from the intercostal space and enters the anterior abdominal wall between the internal oblique and transversus abdominis muscles. After supplying the rectus, it ends as anterior cutaneous branch which supplies the skin of the abdomen. In the midway it gives off the lateral cutaneous branch and supplies the external oblique and latissimus dorsi muscle correspondingly.

The subcostal(T12) nerve gives off an anterior branch which communicates with the illiohypogastric nerve and innervates the pyramidalis muscle.

The illiohypogastric nerve (L1) divides in between the internal oblique and transversus abdominis muscle in close proximity to the iliac crest into lateral and anterior cutaneous branches.Lateral cutaneous branch supplies a part of the skin over gluteal region while its anterior branch supplies the hypogastric region.

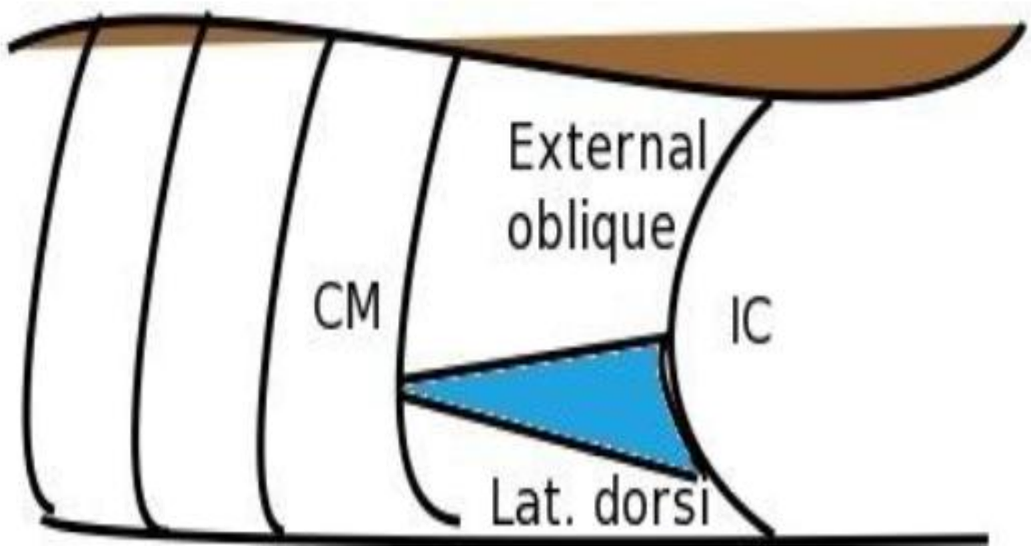
The illioinguinal nerve (L1) and the illiohypogastric nerve communicates with each other in between the internal oblique and transversus abdominis muscle, anterior to the illiac crest. Then it supplies thigh and the genitalia.

INNERVATION OF ANTERIOR ABDOMINAL WALL



3.2 LUMBAR TRIANGLE OF PETIT

The transversus abdominis plane is reached with the anatomical land mark of the lumbar triangle of Petit [5] .The sloping edge over the iliac crest, forms the medial aspect of the lumbar triangle of Petit.. The posterior side of the triangle is formed by the latissimus dorsi muscle. The inferior aspect of the triangle is formed by the illiac crest, and the peritoneum lies deep to the innermost muscle.

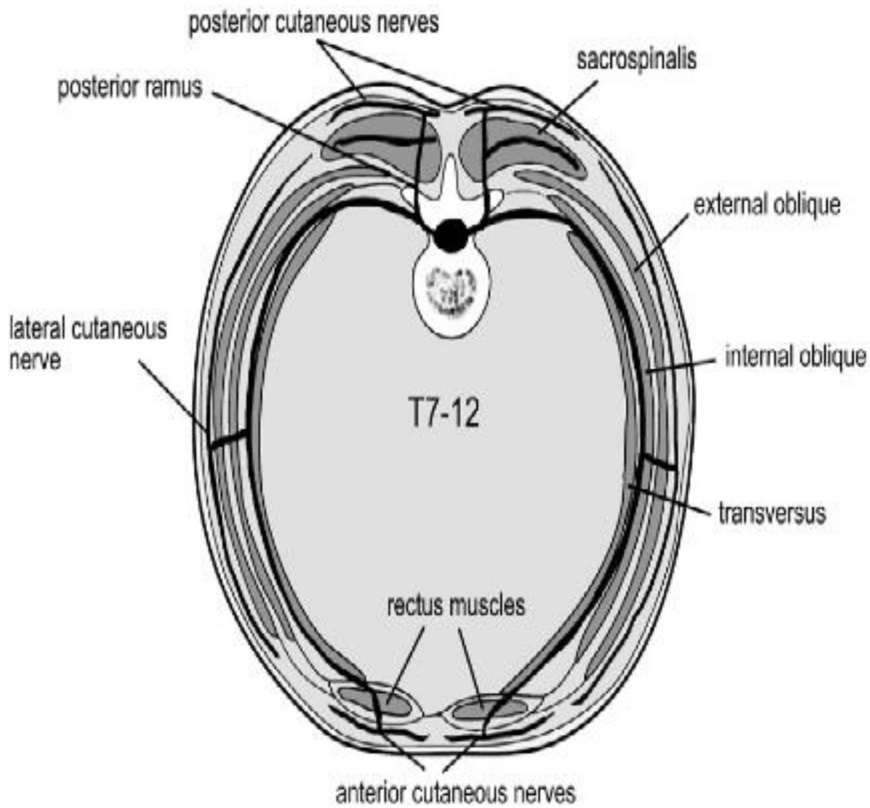


Lumbar triangle of Petit between external oblique muscle and latissimus dorsi.

CM: costal margin, **IC**: illiac crest

3.3 ANATOMY OF TRANSVERSUS ABDOMINIS PLANE

The tranversus abdominis plane exists as a continuous plane in the abdomen. This plane is traversed by the anterior rami of thoracolumbar nerves which innervate the anterior abdominal wall as well-defined neurovascular bundles. Furthermore, Rozen et al.in his anatomical studies found out about the existence of extensive fascial layer, which is nonadherent to the internal oblique muscle and binds down the nerves on its deep surface. [10].


posterior cutaneous nerves
sacrospinalis
posterior ramus
external oblique
lateral cutaneous nerve
internal oblique
T7-12
transversus
rectus muscles
anterior cutaneous nerves

4. POSTOPERATIVE PAIN

4.1 PATHOPHYSIOLOGY OF PAIN

Surgery produces tissue injury which in turn releases numerous inflammatory mediators. Release of these mediators activates peripheral nociceptors, resulting in transduction and transmission of this information to the CNS. The release of neurogenic inflammatory mediators in the periphery induces vasodilatation and plasma extravasation.

Noxious stimuli are transduced by peripheral nociceptors and transmitted by Aδ and C nerve fibers from peripheral sites to the spinal cord where integration of peripheral nociceptive and descending modulatory input occurs.

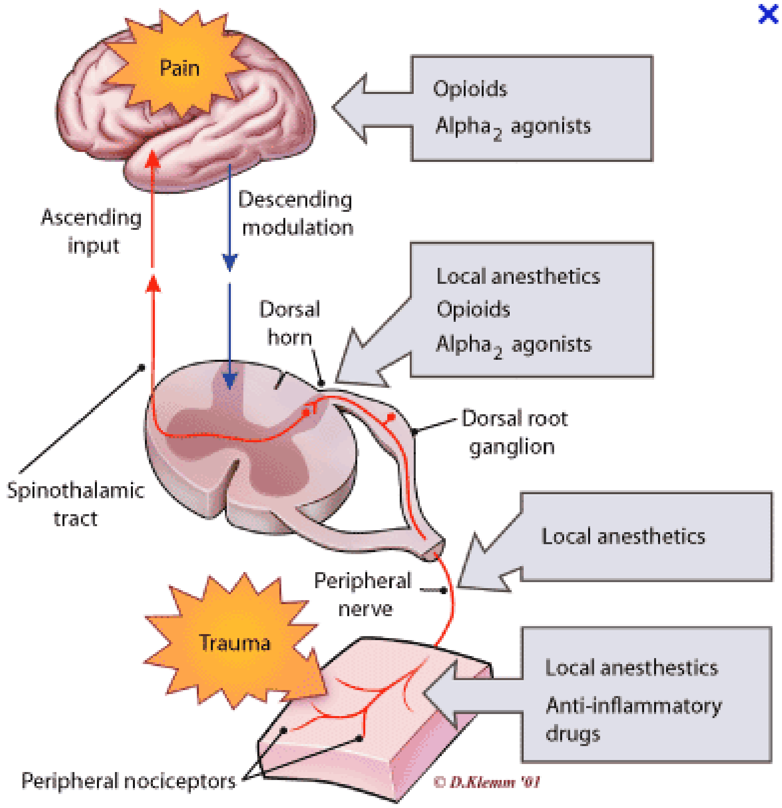
Further transmission of nociceptive information is determined by complex modulating influences in the spinal cord. Some of the impulses pass to the ventral and ventrolateral horns to initiate segmental (spinal) reflex responses, which can be associated with increased skeletal muscle tone, inhibition of phrenic nerve function, or even decreased gastrointestinal motility. Others are transmitted to higher centers through the spinothalamic and spinoreticular tracts, where they induce suprasegmental and cortical responses to produce the perception affective component of pain.

Continuous release of inflammatory mediators in the periphery sensitizes functional nociceptors and activates dormant ones.

Intense noxious input from the periphery may result in central sensitization and hyperexcitability.Such noxious input may lead to conformational changes in the spinal cord which can later cause postoperative pain that is perceived as more painful .

It seems that certain receptors (e.g., *N*-methyl-D-aspartate [NMDA]) may be especially important for the development of chronic pain after an acute injury, although other neurotransmitters or second messenger effectors (e.g., substance P, protein kinase C-γ) may also play important roles in spinal cord sensitization and chronic pain.

PAIN PATHWAYS



4.2 IMMEDIATE EFFECTS OF POSTOPERATIVE PAIN

The perioperative period is associated with a variety of pathophysiologic responses due to nociceptive input.. Uncontrolled perioperative pain may potentiate perioperative pathophysiologies and increases patient morbidity and mortality. Attenuation of postoperative pain with certain types of analgesic regimens decrease perioperative morbidity and mortality.

The dominant neuroendocrine responses to pain involve hypothalamic-pituitary-adrenocortical and sympathoadrenal interactions.

The increased sympathetic tone, catecholamine and catabolic hormone secretion and decreased secretion of anabolic hormones are due to suprasegmental responses to pain. A hypermetabolic, catabolic state occurs as oxygen consumption are increased and metabolic substrates are mobilized from storage depots.

The extent of the stress response depends on the type of anesthesia and intensity of the surgical injury, proportionately. Attenuation of the stress response and postoperative pain may facilitate and accelerate the patient's recovery postoperatively.

The neuroendocrine stress response potentiates detrimental physiologic effects in other areas of the body. The stress response can cause postoperative development of hypercoagulability. Enhancement of coagulation, inhibition of fibrinolysis, increased platelet reactivity and plasma viscosity contribute to an elevated incidence of postoperative hypercoagulable-related events like deep venous thrombosis, vascular graft failure, and myocardial ischemia.

The stress response potentiates postoperative immune suppression, which depends on the severity of surgical injury. Hyperglycemia from the stress response is a factor for poor wound healing and depression of immune function.

Uncontrolled postoperative pain may activate the sympathetic nervous system and hence increases morbidity or mortality. Sympathetic activation can increase myocardial oxygen consumption, which can result in development of myocardial ischemia and infarction and attenuates local metabolic coronary vasodilation. Activation of the sympathetic nervous system may also delay postoperative gastrointestinal motility, resulting in paralytic illeus.

Nociceptors which are activated after surgical trauma may initiate several detrimental spinal reflex arcs. Postoperative respiratory function is markedly decreased after thoracic and upper abdominal surgery. Spinal reflex inhibition of phrenic nerve activity mainly contributes to this decreased postoperative pulmonary function.Patients in pain cannot breathe deeply, not able to cough effectively, and be more susceptible to the development of postoperative pulmonary complications.

Control of acute postoperative pain may attenuate the stress response, sympathetic outflow, and inhibitory spinal reflexes and improves morbidity, mortality, and patient-reported outcomes.

4.3 ASSESSMENT OF PAIN INTENSITY

Assessment of pain can be an easy and straight forward task in acute stages. The visual analogue scale (VAS) and numeric rating scale (NRS) are equally sensitive, for assessment of pain intensity in assessing immediate postoperative pain.

4.3.2 VAS MEASUREMENT:

VAS Scale measures a nature or feelings that cannot be measured directly. This varies from none to an extreme pain.

It is a horizontal line of 10cm/100 mm in length, anchored with description of word at each end. When the patients feel pain of their current state, they mark on the line. The VAS score used to be measured in mm from the left side to the end point patient marked. VAS score has linear scale properties (i.e., the difference in pain between each successive increment is equal).

VAS has been presented in many other ways like vertical lines and lines with extra descriptors.

5. METHODS TO RELIEVE POSTOPERATIVE PAIN

Postoperative analgesia includes systemic and regional analgesic techniques. When a multimodal strategy is used for controlling postoperative pain the analgesic benefits are maximized Many options are available for the treatment of postoperative pain, including systemic (i.e., opioid and nonopioid) and regional (i.e., neuraxial and peripheral) analgesic techniques.

5.1 SYSTEMIC ANALGESIC TECHNIQUES

OPIOIDS

Opioid analgesics are cornerstone options for providing postoperative analgesia. These agents act through μ-receptors in the CNS and at peripheral opioid receptors.The most common routes of postoperative opioid analgesic administration are oral and intravenous. Opioids can also be administered at specific sites such as the intrathecal or epidural space .

5.2 PATIENT-CONTROLLED ANALGESIA

Intravenous PCA optimizes the delivery of analgesic opioids and minimizes the variable effects in individual patients.

Intravenous PCA is acts through a negative-feedback loop .when pain is experienced, the drug is self-administered, and when pain is reduced, there are no demands. Although intravenous PCA use overall appears to be associated with greater satisfaction, there are many methodologic issues in the proper assessment of patient satisfaction.

There is no significant difference in incidence of opioid-related adverse events from intravenous PCA from that of opioids administered intravenously, intramuscularly, or subcutaneously.

5.3 NONSTEROIDAL ANTI-INFLAMMATORY AGENTS

NSAIDs consist of a various compounds which differ in their pharmacokinetic properties. The primary mechanism by which they exert their analgesic effect is through cyclooxygenase enzyme inhibition which synthesizes prostaglandins, which are mediators of sensitization and hyperalgesia. NSAIDs also act by inhibiting spinal COX.

Decreased hemostasis from NSAID use is attributed to platelet malfunction and thromboxane A_2 inhibition.

5.4 SINGLE-DOSE NEURAXIAL OPIOIDS

Administration of a narcotics may be an efficous analgesic agent when administered intrathecally or epidurally. The important factor in determining the clinical pharmacology is the degree of lipophilicity of that particular opioid.

5.5 CONTINUOUS EPIDURAL ANALGESIA

Analgesia delivered through an indwelling epidural catheter is a promising method for management of acute postoperative pain.Postoperative epidural analgesia can provide analgesia superior to that of systemic opioids.

The benefits of perioperative epidural anesthesia-analgesia must be weighed against the risks associated with this technique.

5.6 PERIPHERAL REGIONAL ANALGESIA

A variety of wound infiltration and peripheral regional techniques can be used to enhance postoperative analgesia. Peripheral regional techniques may have several advantages over systemic opioids like superior analgesia and decreased opioid-related side effects and neuraxial techniques like decreased risk for spinal hematoma.

A single shot injection of the drug for peripheral regional techniques may be used primarily for intraoperative anesthesia or as an adjunct to postoperative analgesia. When compared with placebo, peripheral nerve blocks with local anesthetics provide superior analgesia and are associated with reduced opioid use, decreased opioid-related side effects, and improvement in patient satisfaction. The analgesia may last up to 24 hours after injection

Continuous infusions of local anesthetics can be administered through catheters. When compared with use of opioids, use of continuous infusions or patient-controlled peripheral analgesia results in adequate analgesia, reduced opioid-related side effects, and more patient satisfaction.

6. TRANSVERSUS ABDOMINIS PLANE (TAP) BLOCK

In the TAP block the LA is deposited in the plane in TAP plane . Hence the nerves of TAP plane will be blocked. A dull visceral pain will be experienced, due to spasm or inflammation of the organs following surgery.

6.1 INDICATIONS AND USES OF TAP BLOCK:

This technique has wider application and can be used for many lower abdominal surgeries like

(1) appendicectomy

(2) hernioplasty

(3) lower segment cesarean section

(4) Transabdominal hysterectomy

(5) prostatectomy.

(6) Its effectiveness in Lap procedure was proved. For midline incisions and laparoscopic surgeries, bilateral blocks can be given. In such cases dose should calculated carefully without exceeding the safer limits of local anaesthetic agents.

(8) Many reports have also enumerated the usage of TAP blocks.

- Singh et al. concluded from his studies that bilateral TAP blocks was useful in a patient with lung problem and had acute pain after laparotomy, in addition to noninvasive positive pressure ventilation.

- Børglum et al. demonstrated effectiveness of TAP blocks as rescue therapy in patients had undergone major abdominal surgeries and presented with uncontrolled pain.They noted that with their 4-point block patients can be managed well.

6.2 CONTRAINDICATIONS TO TAP BLOCKS

- Unwillingness of patients
- Local site infection
- Coagulopathies

6.3 VARIOUS APPROACHES FOR TAP BLOCK

6.3.1 ANATOMICAL LANDMARK-BASED APPROACH

- Patient is placed in supine position, and the illiac spine is traced with a finger over the iliac crest until an inward dip is found.

- In this point, the skin is pierced and the needle inserted till it touches the bone of the external lip of the illiac crest.
- The needle is advanced over it to feel for a definite “pop”. The single “pop” technique is different from the “double pop” .
- All the blind technique use blunt-tipped needles.

6.3.2 ULTRASOUND- GUIDED TAP BLOCK

- The patient is placed in supine position and the probe is placed in transverse position between the lower intercostal end and illiac crest.
- The needle approach can be either in plane or out of plane approach and the needle is advanced until it reaches the TAP plane
- The needle entry point should be followed by the probe in its superficial path and is then directed towards the needle.
- When the TAP is reached, the plane is confirmed by injecting 2 ml of saline and then the LA solution is injected.
- The TAP is visualized as separation of internal oblique muscle and transversus abdominis muscle and hence expansion of the plane.
- Fine adjustments of the needle angle are not necessary because the probe can be slided to find the crossing point of the tissue plane and

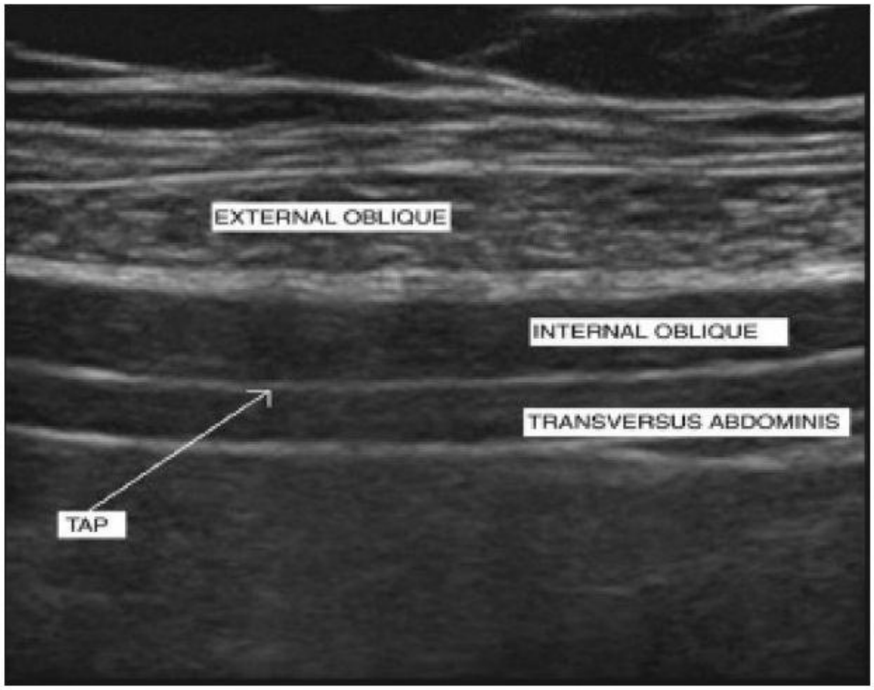
the needle tip. The intent is to first visualize the needle tip in the external or internal oblique muscles before advancing the needle deeper.

- The transversus muscle is thin, so the margin of safety between it and the peritoneal cavity is relatively small.

- For more complete blocks, local anesthetic solutions can be injected into the other layers (between external oblique and internal oblique, and subcutaneous infiltration done between external oblique and skin) when pulling back the block needle.

- For low-volume blocks, the needle tip should be positioned within the fascial plane.

- **ULTRA SOUND VIEW OF TRANSVERSUS ABDOMINIS PLANE**



The transversus abdominis plane

SPREAD OF DRUG IN TRANSVERSUS ABDOMINIS PLANE

Spread of local anesthetic in TAP plane (EO: External oblique muscle, IO: Internal oblique muscle, TA: Transversus abdominis muscle)

6.3.3 TYPES OF ULTRASOUND GUIDED TAP BLOCK

1. POSTERIOR TAP BLOCK

- The probe is placed on the anterior abdominal wall in the transverse position where the three muscle layers are most distinct on ultrasound, that is approximately anterior to the mid axillary line .

- Following skin puncture, the probe is slided anteriorly on the lateral abdominal wall to image the needle. The probe then follows the needle <u>in-plane</u> posteriorly as it advances towards the posterior limit of the TAP.

- Once the needle tip is visualised in the TAP two ml of local anaethetic is injected.

2. ANTERIOR TAP BLOCK:

- For "Anterior" TAP block, the target needle endpoint is more anterior to the posterior limit of the 3 muscles

3. **SUBCOSTAL TAP BLOCK:**

- Good analgesic effect is expected between T10 and L1 in a single shot technique with posterior approach. A higher block upto T7 can achieved with supplementation with a subcostal injection.
- In the subcostal TAP the ultrasound is placed below the costal margin parallel to it.
- The needle lateral to the rectus muscle.

4. SURGEON-ASSISTED APPROACHES

- A laparoscopic-assisted technique was described by Chetwood et al. in which a classic TAP block is performed using laparoscopic camera. After the LA is delivered within the TAP a peritoneal bulge is seen. This technique helps to avoid intraperitoneal injection, one of the major risk of the TAP block.

- Another procedure has been described that is transperitoneal approach. It is performed intraoperatively with needle inserted from inside the abdominal wall, till a single pop sensation is felt to confirm the plane.

- Araco et al. described dissected through the external and internal oblique muscles and thus performed a surgical TAP block .

5. COMPLICATIONS OF TAP BLOCK:

- The published reports regarding this are very rare. Kato suggested et al. noted that toxic plasma levels of lidocaine can occur when using 40 mL of 1%solution.The incidence of vascular injection of local anesthetics in TAP blocks is unlikely, but systemic toxicity is possible. So dosage should be chosen within the therapeutic limits.

- In the literature liver injury caused in TAP blocks are noted.Then further evaluating the patient by laparotomy, the patient was found to have an enlarged liver that. So they a recommended routine palpation of the liver edge when blind right sided TAP technique is used.

- Lancaster and Chadwick came accross liver injury after TAP block performed under ultrasound-guidance. [22] It was mainly due to failure to adequately visualize the full needle while imaging.

- Risk to other solid organs like, the spleen and kidneys are also explained in the literature. at risk during TAP blocks.

LOCAL ANESTHETIC DOSING

DRUG SELECTION BASED ON PATIENTS WEIGHT

	30 kg	50 kg	60- 80 kg
Unilateral (eg. Appendicectomy ,hemicolectomy)	15ml: 0.5% ropivacaine or 0.375% Bupivacaine	25ml: 0.5% ropivacaine or 0.375% Bupivacaine	**30ml:** 0.5% ropivacaine or 0.375% Bupivacaine
Bilateral - Dose to each side (eg: LSCS abdominal Hysterectomy)	15ml: 0.25% ropivacaine or 0.25% Bupivacaine	25ml: 0.25% ropivacaine or 0.25% Bupivacaine	30ml: 0.25% ropivacaine or 0.25% Bupivacaine

There was no comparison in any studies regarding the dosage needed for the TAP block though various local anesthetic agents in different volume and concentration are used in studies.

So, the evidence is lacking to support one regimen over the another. When prolonged duration of analgesia is required TAP catheters can be used which was first described in 2009.

The similarity in pain control between the epidural and TAP catheter analgesia has been shown in a randomized study .But it has not been proved whether the use of a continuous infusion offers any advantage over intermittent boluses in TAP catheters.

7. AN OVERVIEW OF ULTRASONOGRAM

Ultrasound guided regional anaesthesia is relatively new and rapidly growing field of interest. Ultrasound guided nerve blocks were first described in 1978. Earlier study reports have largely focused on brachial plexus blockade under ultrasound guidance. While recent studies examining the efficacy of ultrasound guidance for transversus abdominis plane blocks, celiac plexus and stellate ganglion blocks are promising in providing effective blocks.

Conventional peripheral nerve block techniques that are performed without ultrasound guidance are highly dependent on surface anatomical landmarks for localization of the target nerve. Hence these regional anaesthetic techniques are associated with a reported failure rate of up to 20% because of incorrect needle and/or local anaesthetic placement.

7.1 CHARACTERISTICS OF ULTRASOUND

. The hearing range of human is of 20-20,000 Hz whereas the frequency above 20,000 Hz is called as ultrasound. It is a form of mechanical sound energy which travels as a longitudinal wave through a conducting medium and produces compression and rarefaction alternately. The medical ultrasound which we use is in the range of 2.5-15 MHz.

The average value of speed of sound differs in each biological media and its average is assumed to be 1,540 m/sec in human soft tissues. The sound with a high frequency has a short wavelength and vice versa.

7.2 PRINCIPLES OF ULTRASOUND

When an electric field is applied over an array of piezoelectric crystals present on the surface of transducer, ultrasound wave will be generated. causes Mechanical distortion of the crystals will occur when they are stimulated electrically and produces vibration and generation of sound waves . Thus the conversion of electrical to mechanical energy is called the converse piezoelectric effect.

7.3 COMPONENTS OF ULTRASOUND MACHINE

Ultrasound machine has the following components:

1. A pulser that generates pulsed echo.

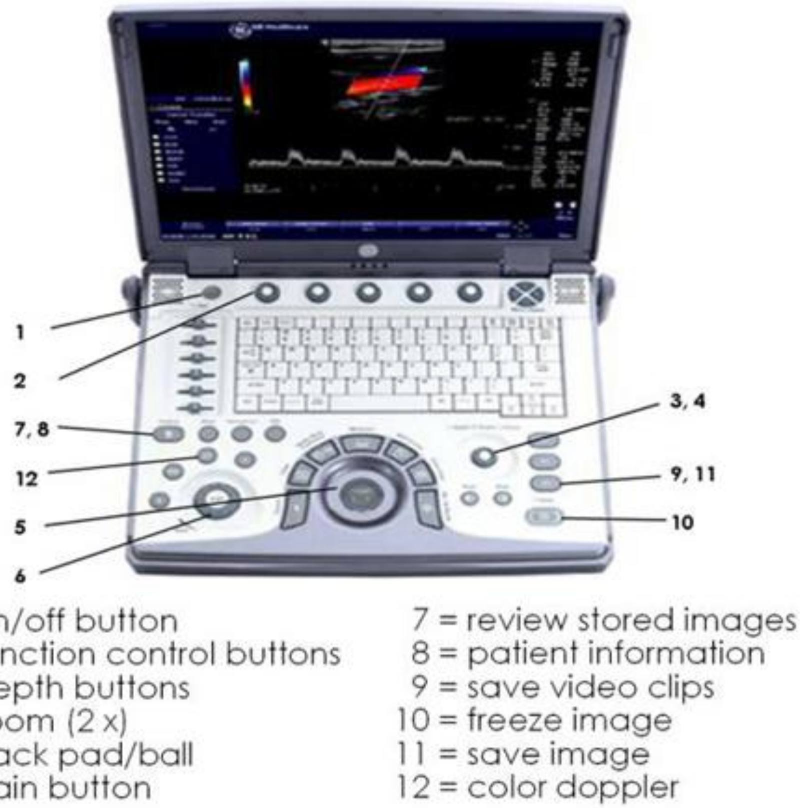
2. A transducer that converts electrical energy to pulsed waves and vice versa .

3. A receiver that detects, and modifies signals returning to the transducer.

4. A display mode.

5. A memory that stores images.

The ultrasound machine which we used for our study was GE LOGIQ e machine- It has an advanced image acquisition technology feature called CrossXBeam™.



7.4.1 VARIOUS TYPES OF TRANSDUCERS AND ITS USES

- The image quality of ultrasound depends on the transducer. The transducer used for nerve blocksis the range of 3-15 MHz. Linear and curvilinear transducers are most useful for nerve imaging.

- The resonance frequency is the frequency at which the piezoelectric transducer converts electrical energy to acoustic energy more effectively and vice versa. It depends on the thickness of the piezoelectric element.

- For superficial structures, high frequency transducers greater than or equal to 7 MHz are used.For deeper structures transducers in the range of 10-15 MHz are used.

- Smaller transducers, are useful for detailed scanning smaller areas.

It is important to remember that:

high frequency = high resolution, limited penetration

low frequency = greater penetration but lower resolution

Different Types of USG Probe

7.4.2 TRANSDUCER HANDLING

One of the essential skills for the operator to acquire with ultrasound is transducer manipulation. Standardized nomenclature has been established for it.

- Sliding: Along the known course of the nerve the transducer is slided using a short-axis view for better identification of the nerve.
- Tilting (side-to-side): The echobrightness of peripheral nerves will vary with the degree of tilt. Optimizing this angle is important to promote nerve visibility.
- Compression. Compression is often used to confirm venous structures. To improve imaging, it brings the structures closer to the surface of the transducer. Soft tissue is subject to compression and therefore estimates of tissue distances can vary.
- Rocking (in-plane, toward/away from indicator). Rocking is necessary to improve visibility of the needle and also the anatomical structures.
- Rotation. Some rotation of the probe will produce true short-axis views rather than oblique or long-axis views.

7.5 VARIOUS IMAGING MODALITIES

1. Initially the imaging modality used with ultrasound was A-mode echo (Amplitude).

2. Today, most ultrasound imaging is performed with B-mode echo (Brightness). This modality uses postprocessing images to assign gray-scale values to pixels from the received echo amplitudes. Frame rates for 2D imaging are approximately 30/sec. Ambient lighting has large effect on visual discrimination. Dim lighting without glare is useful for imaging low-contrast targets.

3. Another useful imaging modality is M-mode echo (Motion). The sampling rate for M-mode is very high (around 1800/sec, but only one spatial dimension).

7.6. BLOCK NEEDLES FOR ULTRASOUND-GUIDED PROCEDURES

Metal needles are hyperechoic and can cause reverberation artifacts .Needle tip visibility is best when the needle path is parallel to the transducer. Under this condition, the needle is perpendicular to the sound beam ,hence strong specular reflections will be produced. As the angle of incidence is increased, the mean brightness will decrease. Bevel orientation influence the needle tip echo, with best visibility with the bevel facing the transducer..Because needle diameters are smaller than the scan plane thickness, larger needles are more echogenic than the finer ones.

Visualization of the needles within the echogenic tissue is difficult. A number of strategies have been proposed to improve needle tip visibility. A low receiver gain can improve detection of the needle tip echo. Spatial compound imaging can help to identify the needle tip when the needle path is at an angle with respect to the transducer. Among the needles developed for use in regional anesthesia, the Hustead needle has a bevel which is more visible in contrast to side port needles.

7.6.1 TYPES OF NEEDLE APPROACH IN REGIONAL TECHNIQUES

Two basic approaches for needle placement are there. With the out of plane technique, the needle crosses the plane of imaging as an echogenic dot. The target is placed in the center of the field. The needle is passed shallow to the target. The transducer can be manipulated by sliding and tilting to follow the needle tip as the needle is advanced. For the out of plane approach it is important to distinguish the needle tip echo from the shaft echo. This can be confirmed by slightly withdrawing the needle to move the needle tip away from the plane of imaging.

With the in-plane approach the full needle tip and shaft are visualized along the axis of the needle. The target is positioned opposite to the imaging field. It is essential to visualize needle tip before the needle is advanced.

7.7 SONOANATOMY OF NERVES

Fascicles of peripheral nerves can be detected with high-resolution ultrasound imaging. The honeycomb architecture is the most distinguishing feature of the nerves .More central nerves, such as the cervical ventral rami, have fewer fascicles and appear monofascicular on ultrasound scans.

Ultrasound transducers with frequencies of 10 MHz or higher are required to distinguish tendons from nerves based on echotexture. One of the powerful technique to identify nerve fascicles is to slide a broad linear transducer over the known course of a peripheral nerve in transverse cross section.

Nerves can be round, oval, or triangular. Although nerve shape can change along the nerve path, the cross-sectional nerve area is constant in the absence of major branching . There is some evidence to suggest that patients with diabetic neuropathy also have enlarged peripheral nerves.

Although direct nerve imaging has led to increase in ultrasound-guided regional anesthesia, the identification of other nearby structures also is critical in this endeavor. These structures permit favorable distribution of local anesthetic so that nerve contact with the block needle is not necessary. Successful drug injections should clarify the borders of the nerve.

7.8. ULTRASOUND ARTIFACTS IN REGIONAL ANESTHESIA

1. When local heterogeneities exist, artifactual bending of the block needle can be observed, the so-called bayonet artifact .Speed of sound artifacts relate to time-of-flight considerations and to refraction at the interface of tissues with different speeds of sound.

2. Sound waves are assumed to take a straight path to and from the tissue. When this does not occur, reverberation artifacts occur from the

multipath echoes. The comet tail artifact is a type of reverberation artifact. Internal reverberations cause the comet tail artifact, which is most intensely observed when the object is perpendicular to the beam. The pleura is a strong reflector that causes comet tail artifact. Reverberation echoes are seen when the block needle is near parallel to the transducer when strong specular reflections are received.

3. Mirror-image artifacts can be observed from reverberation, where the pleura is adjacent to the subclavian artery, Mirror-image artifacts can occur with gray-scale sonographic imaging and spectral and color Doppler flow imaging. Posterior to the subclavian artery, the lung apex, is located which acts as a highly reflective acoustic interface to form this artifact.

4. All reflectors are assumed to be on the central point of the transducer beam. When this is not true, out-of-plane artifacts are observed. Unlike adjacent tissues, biologic fluids do not significantly attenuate the sound beam and therefore can cause acoustic enhancement. Acoustic enhancement artifacts deep to the vessels can be erroneously interpreted as nerves.

5. The most common artifact with ultrasound imaging is contact artifact. Contact artifact is defined as loss of acoustic coupling between the transducer and skin. Scanning gel is applied to exclude air from the transducer–skin interface. Another common cause is trapping of air bubbles under the sterile cover of the transducer.

7.9.2 LIMITS OF ULTRASOUND RESOLUTION

Ultrasound imaging is limited in resolution because the acoustic pulse duration and beam width are finite[13].

Axial resolution along the beam depends on the spatial pulse length (SPL). The axial resolution is at best SPL/2, where SPL = $n\lambda$, with n the number of cycles per pulse and λ the wavelength. Axial resolution is independent of depth.

Lateral resolution depends on depth because the beam width changes with depth. The effective beam cross section increases with transmission output or receiver gain. An increase in receiver gain causes the line widths to increase because the receiver now detects echoes at more lateral positions from the central ray.

7.9.3 SIDE EFEECTS

1. Ultrasound imaging can cause warming of tissues through absorption of sound waves. The propensity of ultrasound to cause heating is estimated by thermal index. The bone thermal index (TIB) and soft tissue thermal index (TIS) track maximum temperature increase in those respective tissues.

2. Transmission of sound waves can also cause cavitation. Cavitation occurs when dissolved gas becomes microbubbles. This results in extravasation of blood cells into the lung. The mechanical index is the best index to indicate this effect. Pulsed-echo ultrasound does not produce cavitation because the pulses are very short. However, no adverse biological effects have been confirmed for diagnostic ultrasound.

8. PHARMACOLOGY OF BUPIVACAINE

8.1 STRUCTURE OF BUPIVACAINE

Bupivacaine HCL (1-butyl-2', 6' pipecoloxylidide hydrochloride) is a long acting amide local anesthetic.

It was first synthesized in 1957 by Ekernstam at A.B. Bafors Laboratories in Molndel,Sweden.

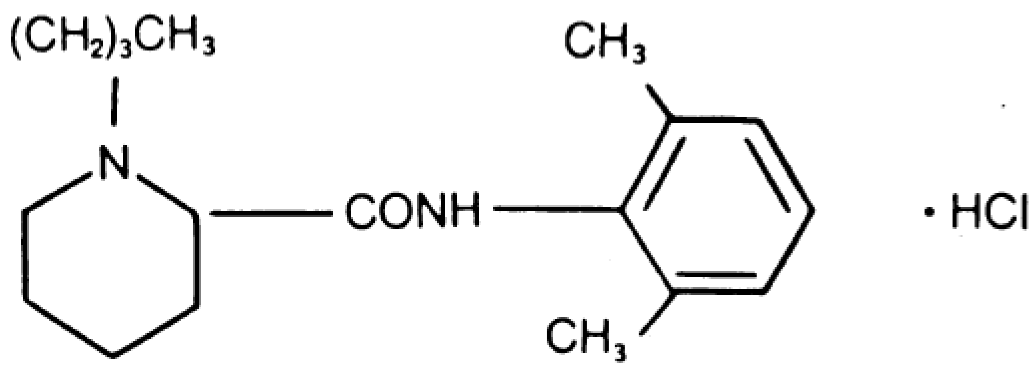


Figure 1
Chemical Structure of Bupivacaine

8.2 MECHANISM OF ACTION

Impulse blockade by local anesthetics is in the following order

1. Local anesthetics deposited near the nerve penetrates the nerve sheath and act on it.

2. Local anesthetic molecules penetrate the nerve's axon membranes and the speed and extent of it depends on a particular drug's pK_a and its lipophilicity.

3. Local anesthetics bind to sites on the voltage-gated Na^+ channels preventing opening of the channels and inhibits the conformational changes of the channels. They also bind in the channel's pore and also occlude the sodium ions path.

4. During onset of and recovery from local anesthesia,there is is incomplete and partial impulse blockade producing an use-dependent binding to Na^+ channels..

8.3 PHYSICO-CHEMICAL PROPERTIES OF BUPIVACAINE

Local anesthetic	**pKa**	**% Ionized (at pH 7.4)**	**Partition coefficient (lipid solubility)**	**% Protein binding**
Bpivacaine	8.1	83	3420	95%

ANESTHETIC POTENCY

Hydrophobicity is the primary determinant of anesthetic potency because the anesthetic molecule must penetrate into the nerve membrane and bind at a partially hydrophobic site on the Na^+ channel. Differences between in vitro and in vivo potency may be related to a number of factors, including local anesthetic charge and hydrophobicity (which influence partitioning and transverse diffusion across biologic membranes) and vasodilator or vasoconstrictor properties (which influence the initial rate of vascular uptake from injection sites into the central circulation).

8.4 ONSET OF ACTION

The onset of block is related to the physicochemical properties of the individual agents. In vivo latency is also dependent on the dose or concentration of local anesthetic used. That is 0.25% bupivacaine has a slower onset of action, and if the concentration is increased to 0.75% there is significant acceleration of its anesthetic effect.

8.5 DURATION OF ACTION

The duration of action of the various local anesthetics differs markedly. Tetracaine, bupivacaine, ropivacaine, and etidocaine have the longest durations.

The duration of anesthesia depends upon the peripheral vascular effects of the drugs. Many local anesthetics have a biphasic effect that is vasoconstriction at lower concentration and vasodilation at higher concentration. However, differences exist in the degree of vasodilator activity of the various drugs. The topical local anesthetic formulation EMLA vasoconstricts cutaneous vessels initially and through most of the first hour of application, but vasodilation is observed after 2 or more hours of application.

8.6 VARIOUS FACTORS INFLUENCING ANESTHETIC ACTIVITY:

8.6.1 DOSAGE OF LOCAL ANESTHETIC

The volume of anesthetic solution probably influences the spread of anesthesia.In selecting the volume and concentration for a specific block in a particular patient, clinicians must balance the risk of adverse effects from excessive dosing (systemic toxicity, excessive motor or autonomic blockade, etc.) against the increased risk of block failure if an inadequate volume or concentration is chosen. The degree to which additional volume can compensate for imprecise needle placement varies among different blocks.

With the advent of very precise needle placement using ultrasound-guided blockade, it has become clear that the median effective volume for obtaining successful blockade can be achieved with smaller volumes than have been recommended from some previous clinical series based on traditional methods of needle localization. As limited by toxicity considerations, the aim in most clinical situations should be to choose doses that provide high success rates; that is, a dose effective in 95% of patients (ED_{95}) is generally a more relevant guide to dose selection than an ED_{50} dose. We should not aim for failure 50% of the time.

8.6.2 SITE OF INJECTION

The rapid onset and shortest duration of action occurs when local anesthetics are administered intrathecally or subcutaneously. After brachial plexus blockade,the duration of analgesia will be much longer. The differences in the onset and duration of anesthesia and analgesia are due the rate of diffusion and vascular absorption of the drug

8.6.3 MIXTURES OF LOCAL ANESTHETICS

Mixtures of local anesthetics are sometimes used in an effort to overcome the short duration of action of certain rapidly acting agents. Mixtures of chloroprocaine and bupivacaine theoretically offer significant clinical advantages. The use of catheter techniques for many forms of regional anesthesia makes it possible to begin with a rapid-onset local anesthetic and then follow with an infusion of either a shorter-acting or longer-acting local anesthetic thereafter.

8.7 PREGNANCY

The effects of pregnancy on local anesthetic potency are due to combined effect of mechanical factors associated with pregnancy and direct effects of hormones, especially progesterone, on the conduction blockade of nerves by local anesthetics per se. Hormonal alteration is the more important of these two factors. The pregnant women myocardium is more sensitive to local anaesthetics. Hence the dosage of local anesthetics should be reduced in patients in all stages of pregnancy.

9. REVIEW OF LITERATURE:

1. McDonnell et al [7],[11] - conducted the first study and reported that a single- shot TAP block was effective even in supra-umbilical incision surgeries. They also performed TAP block through the Petit's triangle using local anaesthetic and dye, and demonstrated using MRI,definite spread of dye in the transverse plane from iliac crest to the costal margin. In addition, their study on volunteers achieved sensory block upto T7 dermatome level. To support this, he placed a catheter at the same depth as the subcostal approach with the skin mark at 10 cm or more. This eliminates the need for a subcostal TAP block for supraumbilical incisions.He performed TAP block in patients who underwent Cesarean section with 0.75% ropivacaine 1.5 mg/kg and compared it with the total dose of morphine used in the controls.He found out that the total dose of morphine injected to the patients was reduced by the TAP block .

2. Siddiqui et al.[28]in his analysis of Seven randomized, double-blinded studies of both blind and ultrasound guided TAP technique for postoperative analgesia in infra umbilical surgeries demonstrated average and significant reduction in IV PCA requirement as a part of multimodal analgesic regimen. He also demonstrated reduced VAS score both at rest and movement in the early postoperative period. He also found out the reduced incidence of postoperative nausea, vomiting and sedation.

3. ***S. A. Patel et al***[10]- In their studies concluded that narcotic usage is decreased in the immediate postoperative period among women who received a TAP block immediately after cesarean delivery compared to those who received intrathecal or epidural narcotics. Specifically, there was 34% reduction in oral narcotic dosing in patients who received a TAP block.

4 Bharti et al[24] in his randomized study of forty patients who underwent colorectal surgery, compared TAP block with 0.25% bupivacaine to standard postoperative analgesic regimen with narcotics and opioids.The Tap group had a significant reduction in narcotic usage and reduced pain scores both at rest and movement

5 Tran et al. in his study based on anatomical dissection found out that the drug injected under ultrasound-guidance spread in the TAP which is present in between the transversus abdominis and internal oblique muscles. Dye was injected into the TAP in each hemi-abdominal wall and dissection was done to determine the extent of dye spread and also the nerve involvement.

*6**. El-Dawlatly et al**[19].* Studied about US guided TAP block with 0.5% bupivacaine 15 ml given bilaterally and found out that the postoperative analgesia by means of IV-PCA, was significantly less in the group of patients who received the US-TAP block after general anesthesia than the control group.

*7. **J. M. Baaj et al** [18]* - demonstrates the analgesic efficacy of ultrasound-guided TAP block after cesarean delivery. The block reduced the postoperative pain, total morphine consumption, antiemetic drugs, and improved patient's satisfaction and quality of pain relief

*8**. Zorica et al*** discussed safety of TAP block .There are reports of visceral damage when the needle went too far like liver injury9, colon rupture and another reported complication is transient femoral nerve Palsy

*9. **Borglum et al**.[25]* demonstrated that TAP blocks can be used as rescue therapy in patients with uncontrolled pain who had undergone major abdominal surgery. They found out that their 4-point TAP block was significantly effective in managing pain, decreased narcotic consumption, enabling quicker discharge.

10. ***Rozen et al.***[26] concluded from their studies that there was an extensive nonadherent fascial layer, deep to the surface of the internal oblique and that layer bind down the nerves on its deep surface, but is located superficial to the transversus abdominis muscle . They also found that, the nerve segments from T6-L1 innervate the abdominal wall and the individual nerve segments branch and communicate extensively with other nerve segments when they travel in the TAP.

11. **Sforza et al**.[23] in his study regarding TAP block effectiveness in abdominoplasty ,has found out the advantages of the block in terms of narcotic sparing effect,marked analgesic effect than that of controls . But the information of the study is difficult to generalize, because the datas reported are without standard deviations and confidence intervals, and the restricted follow-up time .

10. AIM OF THE STUDY

The aim of our study is to compare the efficacy of 0.25%Bupivacaine and 0.375% Bupivacaine in ultrasound-guided TAP (**Transversus Abdominis Plane**) block for postoperative analgesia in lower segment cesarean section under standardized general anaesthesia.

11. MATERIALS AND METHODS

This study was conducted in Government Kilpauk Medical College after obtaining ethical committee approval of our institute.40 Parturients belonging to ASA physical status I & II undergoing elective Lower segment cesarean section were enrolled in our study. All the patients were explained about the purpose and details of the study. Informed written consent was obtained from each patient. This study was conducted between the period of July 2012-October 2012

11.1 STUDY DESIGN

Our study was a prospective double blinded randomized control study.

11.2 PATIENT SELECTION CRITERIA

All these 40 patients were examined, evaluated clinically and biochemically and made familiar with study plan were assessed for Elective LSCS after considering the inclusion and exclusion criteria under General Anaesthesia with physical status ASA I&II and were grouped into two Groups with 20 patients in each Group.

Inclusion Criteria:

- ASA Class I & II
- Patients undergoing elective LSCS under pfannensteil incision

Exclusion Criteria:

- Age<18 years&>35 years
- BMI>30
- ASA Class III & IV (Severe PIH, Stenotic Valvular Heart disease)
- Emergency Surgery (Includes Fetal distress, threatened rupture, hemodynamic compromise)
- History of allergy to local anaesthetics
- Patients not willing for TAP block/General Anaesthesia
- patients with a history of diabetes mellitus
- patients undergoing a vertical midline skin incision
- Psychiatric patients
- Bleeding diathesis
- Difficult Airway

11.3 STUDY GROUP SELECTIONS

The 40 selected and assessed patients planned *for Elective LSCS* under General Anaesthesia with physical status ASA I&II were randomly divided into two groups of 20 patients each, as

GROUP A :-20 patients received bilateral TAP Block with 15ml of 0.25% Bupivacaine on each side labeled as Standard Drug solution A.

GROUP B :-, 20 patients received bilateral TAP Block with 15ml of 0.375% Bupivacaine on each side labeled as Study Drug solution B.

The analyzer then allotted them into 2 groups. 20 patients who had received 30ml of 0.25%bupivacaine were assigned to group A or study group. Remaining 20 patients who had received 30ml of 0.375% bupivacaine were allocated to group B .All the patients were given test dose of Bupivacaine pre-operatively.

11.4 BLINDING TECHNIQUE

Both the drug solutions were prepared as per methodology and kept in 20ml identical syringes by Anaesthesia assistant and was labeled as Solution A & Solution B . Then the analyzer who is unaware of the concentration of the drug in the syringe administer it during the TAP block and observe and records the results So neither the patient who is receiving it nor the person giving it, did not know what is present inside the syringe.Hence it is a double blinded technique.

11.5 STUDY PERIOD:

The study period was from the time of initiation of block upto the requirement of first rescue analgesic dose.

11.6 OBSERVATION PERIOD:

Patients in both the groups were monitored and observed in the PACU for 24 hours for any side effects and complications.

11.7 MATERIALS USED IN OUR STUDY:

- Ultrasound machine with a transducer (7-13 MHz)
- Sterile gloves
- Ultrasound probe cover
- Antiseptic solution for skin disinfection
- ultrasound gel
- 23 gauge spinal needle
- 20ml syringe with injection tubing

11.8 PARAMETERS OBSERVED IN OUR STUDY:

- Baseline vital parameters- PR, BP, SpO_2
- Time of onset of pain after extubation
- Block given Time
- Pain assessment – VAS@ 2 min,4 min,6 min, 8 min, 10 min, 15 min, 20 min,25 min, 30 min, 1hr, 2hr, 3hr, 4hr, 5hr, 6hr, 7hr, 8hr, 9hr and 10hr.
- Time of onset of analgesia.
- Patients comfort and vital monitoring.
- Sedation Score.
- Incidence of side effects
- Incidence of complication
- Time of First Rescue analgesic requirement.
- Duration of Analgesia

RESCUE ANALGESIA USED

When the patient complained of pain injection Tramadol 2mg per Kg was given intra muscularly

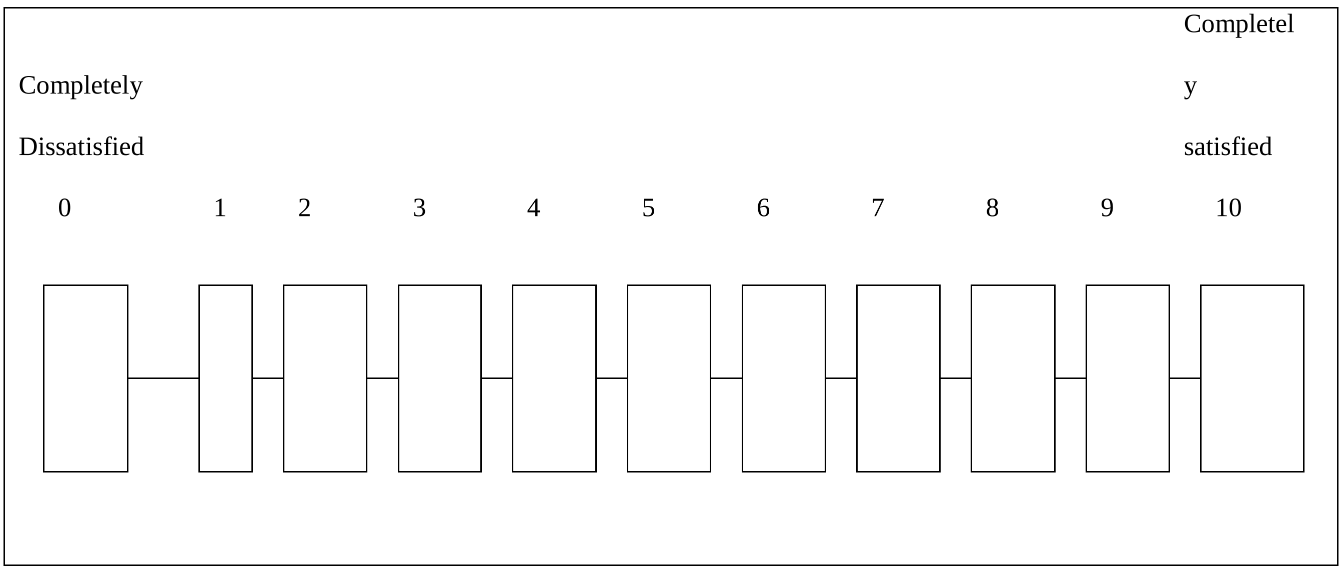
SCALES & SCORES USED:

VISUAL ANALOGUE SCALE:

" Please make a mark on this line that describes how much pain you are having"

No 0___1___2___3___4___5___6___7___8___9___10 Worst pain imaginable

PATIENT SATISFACTION SCALE:



11.8 MONITORING:

Standardised General Anesthesia was administered as below in both the Groups:

- observation of baseline vital parameters
- vital parameters monitoring
    - Pulse oximetry
    - Non invasive bood pressure
    - Electrocardiogram
    - End tidal CO_2
    - Urine output monitoring
    - Temperature monitoring
- premedication – Inj. Glycopyrrolate 0.2mg iv

- rapid sequence induction with Inj. Propofol and Inj. Succinyl choline
- cricoid pressure (Sellick's manouvere)- released after inflating ET tube cuff
- intubation with 6.5 or 7.0mm cuffed oral ET tube.
- Maintenance 0f General Anaesthesiaalong with IPPV: –

  before baby delivery : 50:50 of O2: N2O + Inj.Atracurium –after baby delivery : 30:70 of O2: N2O + Inj.Fentanyl 2micro gram/kg
- Reversal of neuromuscular blockade- Inj.Neostigmine & Inj.Glycopyrrolate

- Post op monitoring and observation

11.9 CONDUCT OF STUDY:

11.9.1 PRE OPERATIVE INSTRUCTIONS:

All term pregnant patients were posted for elective lower segment cesarean section , after a complete medical history and examination and a proper preoperative assessment. They were explained about this study in their own language and written informed consent was obtained from them for inclusion into this study. Then, they were taken up for the study, after satisfying the inclusion and exclusion criteria.

All patients were advised overnight fasting. Patients in both the study and control groups received Tab. Ranitidine 300mg on the night before surgery.

11.9.2 CONDUCT OF STANDARDIZED GENERAL ANESTHESIA AND TAP BLOCK:

On the day of surgery, the patients were shifted to the operating theatre. In the premedication room, all the baseline vital parameters were recorded. All patients were premedicated with Inj. Glcopyrrolate 0.2mg just before induction. A good intravenous line was established with 18G venflon.

On shifting the patient to the operating table, routine monitors – pulse oximetry , non invasive blood pressure, electrocardiogram , capnography, temperature were connected. Patients were explained beforehand, about the cricoid pressure that would be given and advised not to get panic. The patients were preoxygenated for five minutes with 100% oxygen . Patients in both the groups were induced by Rapid Sequence Induction using Inj. propofol 2mg/kg. Once the patient loses consciousness, the cricoid pressure (sellick's manouvere) was applied and maintained by a trained personnel. Inj.Succinyl choline 2mg/ kg was given ,maintaining the cricoid pressure. They were intubated using 6.5 or 7mm ID size endotracheal tube, under direct larnygoscopic vision of the glottis. The cricoid pressure was released once the tracheal tube cuff was inflated. The endotracheal tube was secured after confirming bilateral equal air entry.

Anesthesia was maintained with 50%: 50% oxygen and nitrous oxide, non-depolarizing muscle relaxant. After delivery of the baby, Inj. Fentanyl1µg/kg, Inj. Syntocinon 10U were given and anesthesia was maintained with 70:30 nitrous oxide in oxygen. All patients maintained hemodynamic stability in the intra operative period.

At the end of surgery,,after the patient showed spontaneous breathing efforts, the neuromuscular blockade was reversed with Inj.Neostigmine40µg/kg and Inj.Glycopyrrolate 10µg/kg iv. All patients were extubated on table uneventfully, after they satisfied the extubation criteria.

11.10 ASSESSMENT OF PAINS SCORE

After extubation the patients were observed for pain on a 10 cm VAS. When the patients VAS pain score recorded was 3/10 Ultra sound guided TAP block was initiated bilaterally.

11.11 CONDUCT OF ULTRA SOUND GUIDED TAP BLOCK

PREPARING A STERILE TRANSDUCER FOR TAP BLOCK

1. The ultrasound transducer is placed in a sterile sheath.
2. Adequate gel is applied between the transducer and the sheath covering.
3. There should not be any wrinkle or trapped air inside the sheath which can impede full contact. A sterile rubber band is wrapped

around the transducer to avoid any transducer movement inside the sheath while scanning.

4. Sterile gel should be applied over the skin surface to avoid any trapping of air between the transducer and skin

11.11.1 PROCEDURE OF TAP BLOCK

The TAP Block technique used was posterior approach.

- All sterile aseptic precautions were adapted and drapped with sterile linen before performing the procedure.
- The investigator was scrubbed and the ultrasound probe was covered with a sterile plastic cover and placed in the midaxillary line just superior to the iliac crest .
- After identifying the abdominal layers, the transversus abdominal plane was reached by using an 23 gauge spinal needle. Correct placement of the needle tip was confirmed by injecting 1-2 ml of saline bilaterally.
- A bolus dose of 15 ml of Drug solution A was administered bilaterally for Group A and 15 ml of Drug solution B was administered bilaterally for Group B.

- Patients vital parameters like pulse ,respiratory rate, saturation , blood pressure, were recorded.

11.11.2 OBSERVATION AFTER THE TAP BLOCK

The parturients were observed for pain on a 10cm VAS after initiation of block. In the initial two hours, they were monitored in recovery room followed by 24 hours observation in PACU. Pain scores were observed at 2min, 4min, 6min, 8min, 10 min, 15 min, 20 min, 25 min, 30min & then every ½ hourly intervals upto 24 hrs on a 10cm VAS (‘no pain’ at 0 cm end and ‘worst pain ever’ at 10cm end) after the initiation of block. The observer assessing pain was kept blinded for the concentration used. If the VAS score failed to decline atleast by 1cm even after 30 min of TAP block, the patient was given intramuscular tramadol 100mg i.m. and was excluded from the study.

11.11.3 PARAMETERS OBSERVED

1. The onset of analgesia is the time from injection of the study solution to first reduction in pain intensity by at least 1cm in VAS

2. The duration of analgesia is defined as the time between the onset of analgesia and return of VAS to 3cm (after which patients were given i.m. tramadol & the study was concluded).

3. If any patient demanded pain relief before the study could be completed they were also given i.m. tramadol 2mg/kg & were excluded from the study.

4. The overall satisfaction of the patient was assessed with a 10 cm scale of VAS patient Satisfaction (‘no satisfaction’ at 0 cm end and ‘the best satisfaction’ at 10 cm end).

5. Sedation was assessed when the VAS score reached the minimum (using Modified Ramsay sedation score).

Patients vitals (RR,NIBP,PR.SPO2) were monitored 24 hours following TAP block. The occurrence of nausea ,vomiting, allergic reactions and any adverse reactions were noted up to 24 hours following administration of the study solution.

12. OBSERVATION AND RESULTS:

In our randomized prospective double blinded study, a total of 40 patients were studied, with 20 patients in each group. The statistical analysis for demographic profile were done with unpaired t test.

Table 1: PATIENTS CHARACTERISTICS

	Group A	**Group B**	**p value**
AGE(yrs) (mean±SD)	25.95±2.911	25.75±2.712	0.8
HT(cm) (mean±SD)	159.85±4.923	159.50±5.472	0.8
WT(kg) (mean±SD)	58.40±5.165	58.90±6.307	0.7
BMI(kg/m^2) (mean±SD)	22.83±1.37	23.12±1.85	0.5

The demographic profiles like age, weight, height, BMI were compared in both groups. As per Table 1 and there was no statistically significant differences in these profiles between the two groups.

COMPARISON OF MEAN AGE (YEARS) BETWEEN GROUPS

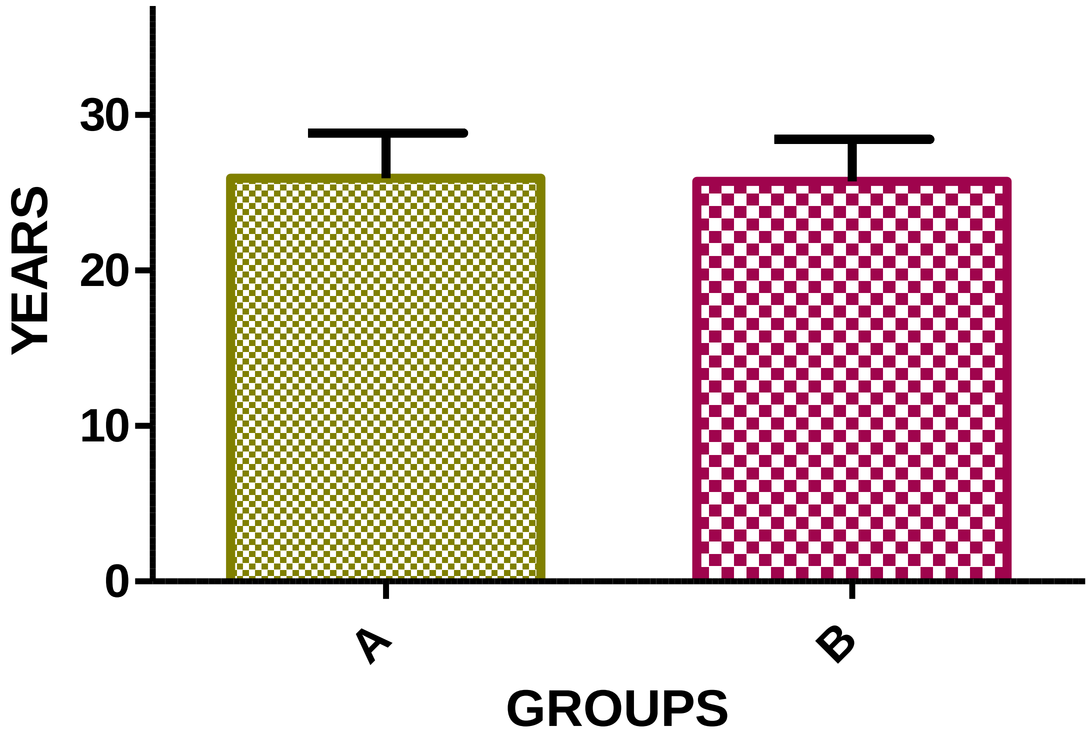


Figure: 1

As per Figure 1, Mean age (years) between the two groups (A and B) was compared. Error bar represents the standard deviation (SD). Unpaired t test was used to compare the two groups. There was no statistically significant difference between the groups ($p>0.05$)

COMPARISON OF MEAN HEIGHT (cm) BETWEEN GROUPS

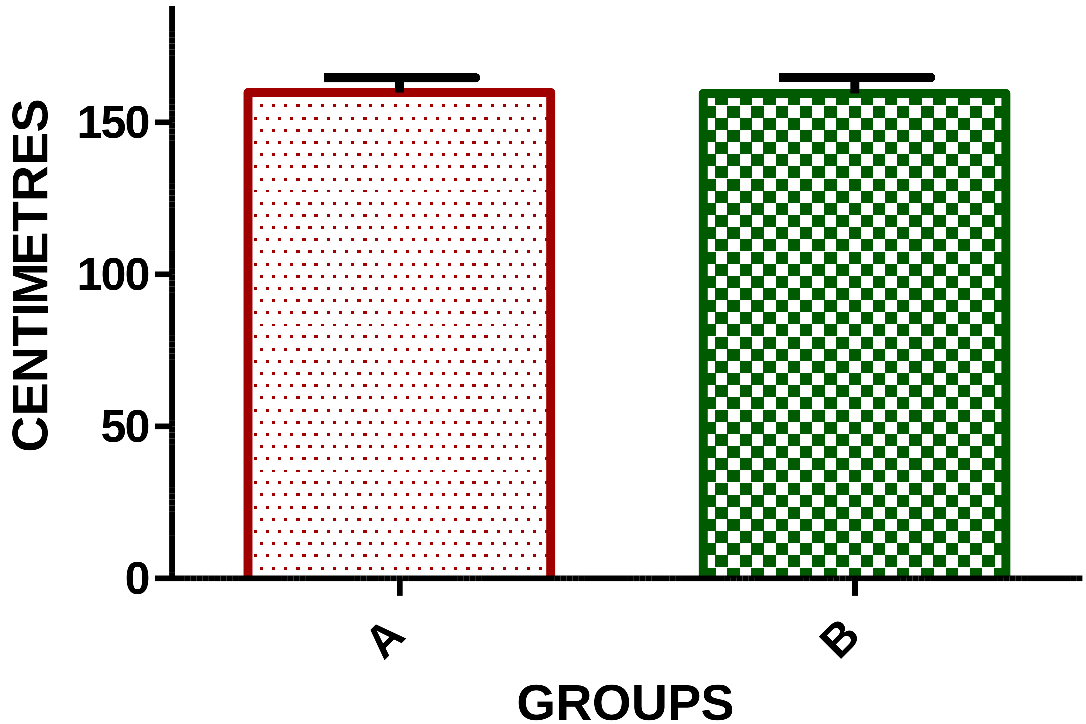


Figure: 2

As per Figure 2, Height (cm) between the two groups (A and B) was compared. Error bar represents the standard deviation (SD). Unpaired t test was used to compare the two groups. There was no statistically significant difference between the groups ($p>0.05$)

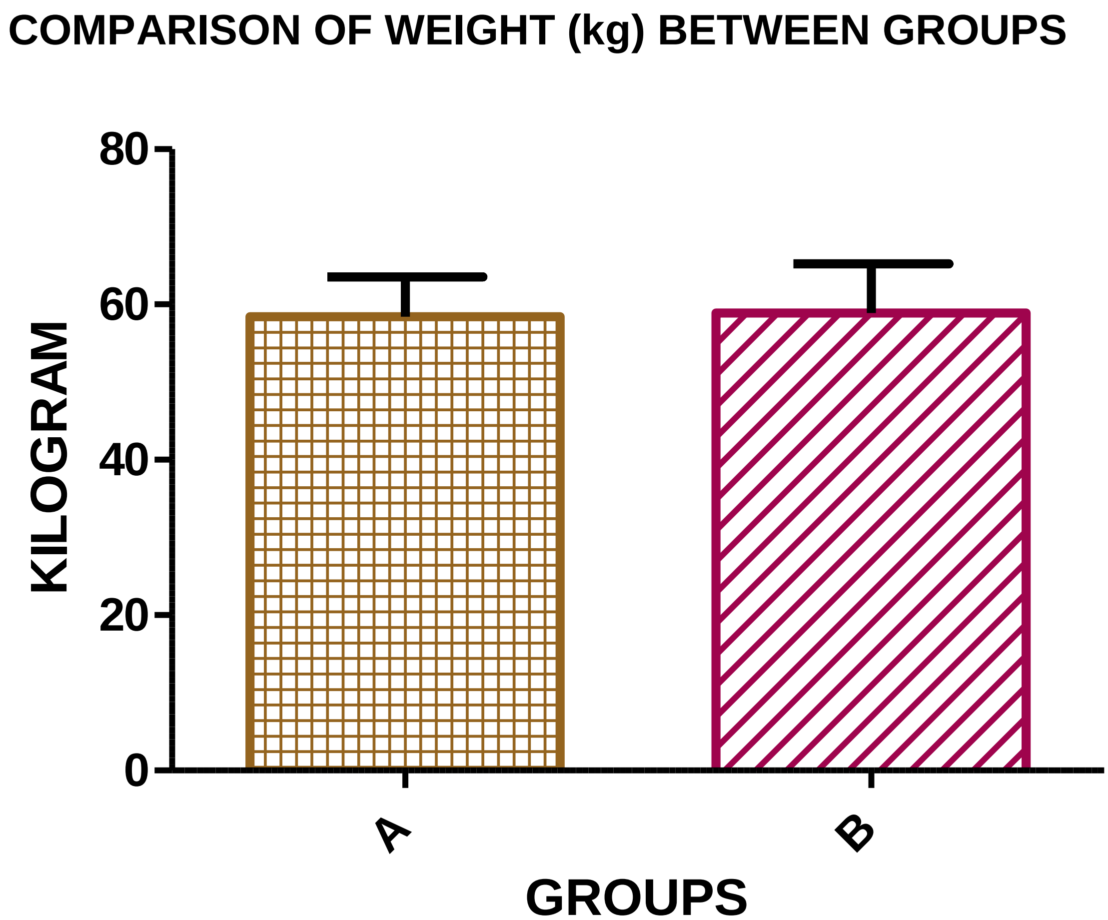


Figure: 3

As per Figure 3, Mean weight (kg) between the two groups (A and B) was compared. Error bar represents the standard deviation (SD). Unpaired t test was used to compare the two groups. There was no statistically significant difference between the groups ($p>0.05$)

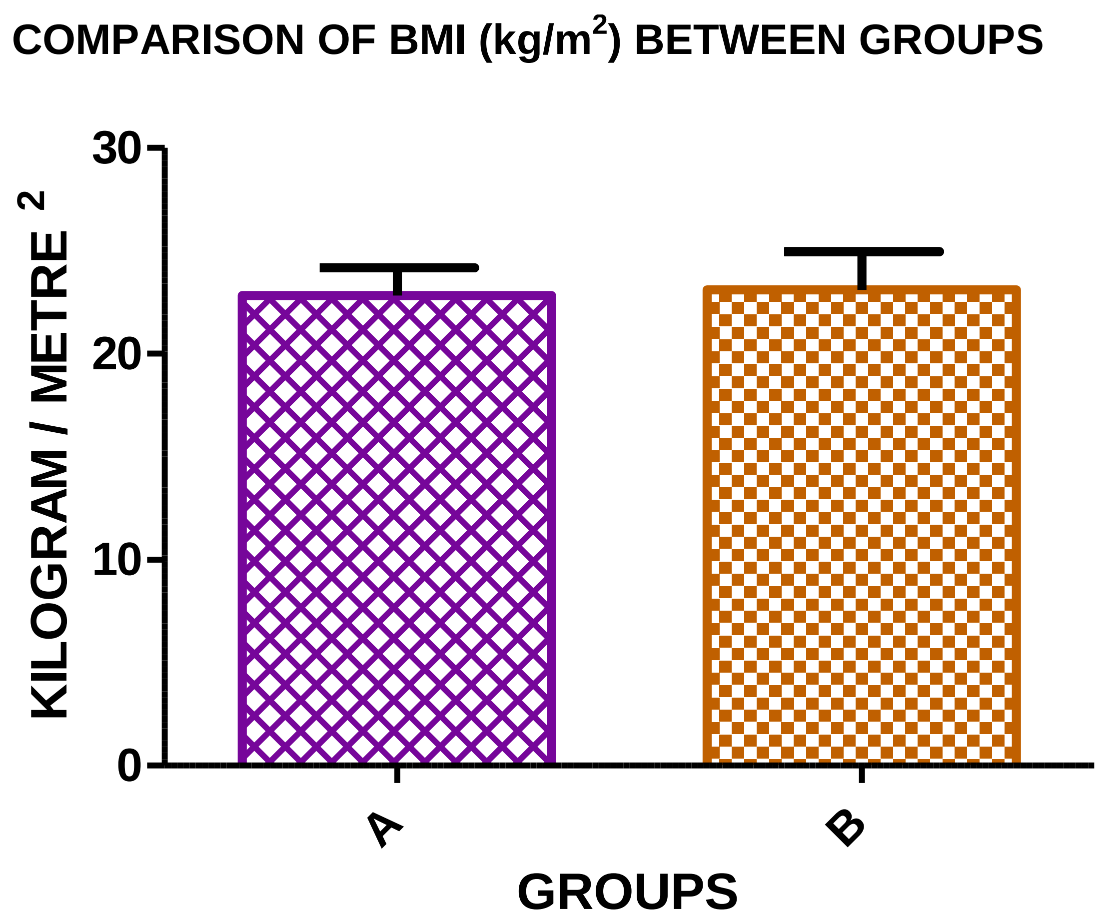


Figure: 4

As per Figure:4, Mean body mass index (kg/m^2) between the two groups (A and B) was compared. Error bar represents the standard deviation (SD). Unpaired t test was used to compare the two groups. There was no statistically significant difference between the groups ($p>0.05$)

TABLE: 2

A	Group A	Group B	p value
sDURATION OF SURGERY(min) (mean±SEM)	51.50±5.472	48.60±1.055	0.08

As per Table 2, there was no significant difference between two groups depending on duration of surgery.

COMPARISON OF DURATION OF SURGERY (MIN) BETWEEN GROUPS

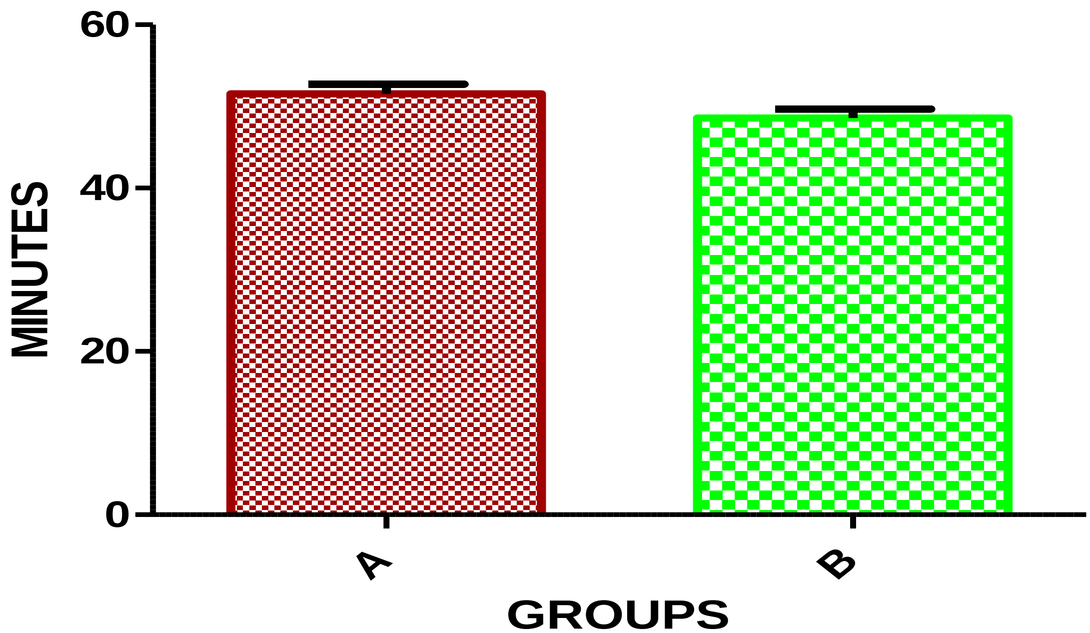


Figure: 5

As per Figure 5, Mean duration of surgery (min) between the two groups (A and B) was compared. Error bar represents the standard error of mean (SEM). Unpaired t test was used to compare the two groups. There was no statistically significant difference between the groups (p>0.05)

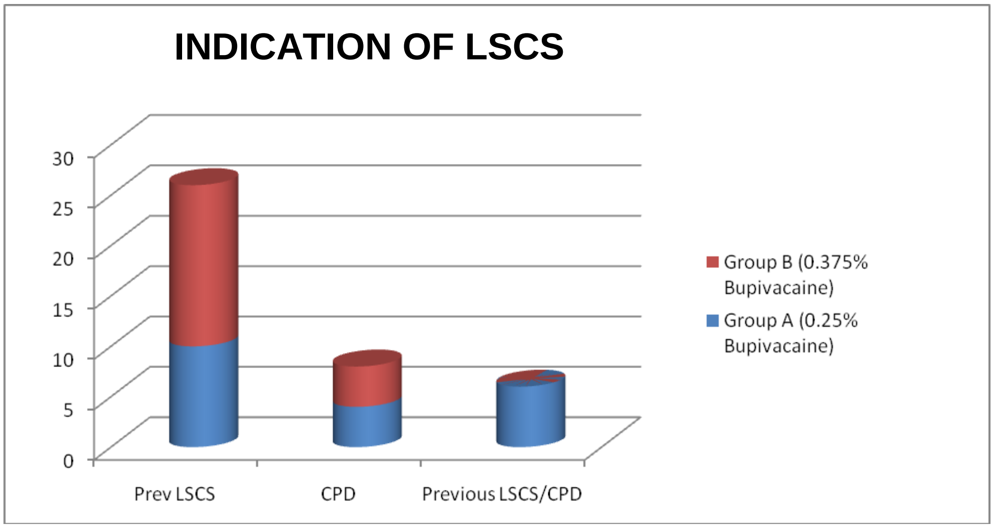


Figure: 6

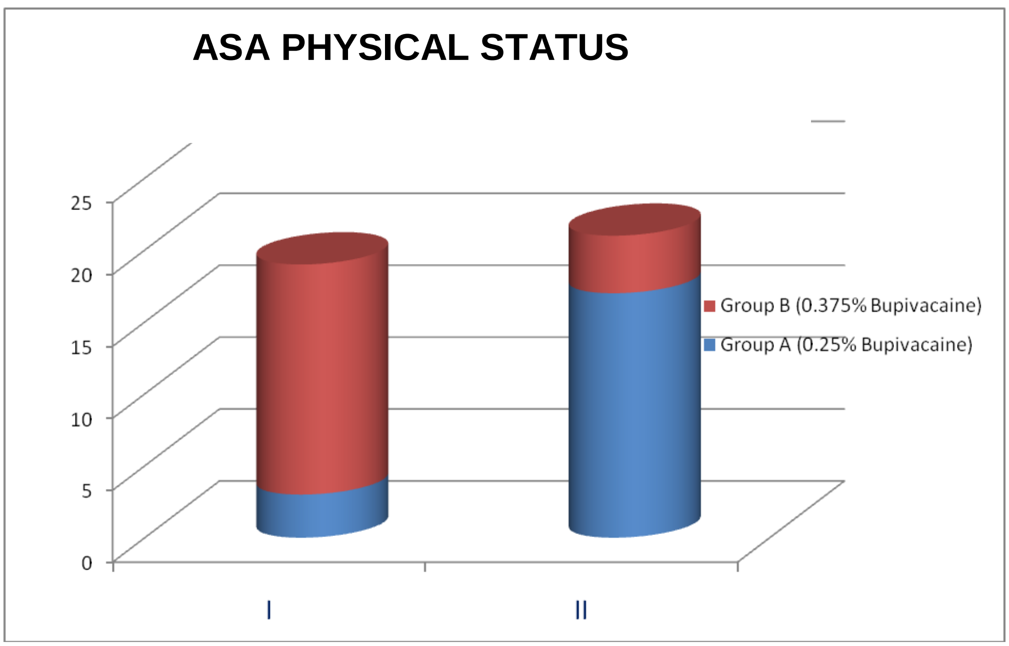


Figure: 7

As per Figure 6 & 7 ASA physical status, history of previous abdominal surgery does not give any significant difference in the datas between two groups. Similarly incision methods, surgeon and operation time were compared in both groups and no significant difference was noted.

OBSERVED PARAMETERS

TABLE 3

	Group A	**Group B**	**p value**
ONSET OF ANALGESIA(min) (mean±SEM)	15.40±4.109	14.50±.881	0.4
DURATION OF ANALGESIA(min) (mean±SEM)	365.00±25.854	544.50±9.017	< 0.0001

As per Table 3,

1. The mean time of onset of analgesia (min) was compared between the two groups and there was no significant difference between the two groups. (Group A vs Group B) (15.40±4.109 vs 14.50±.881) ($p>0.05$).

2. The mean duration of analgesia (min) was compared between the two groups and the mean duration was significantly lower in the Group A compared to Group B. (365.00±25.854 vs 544.50±9.017) ($p< 0.0001$)

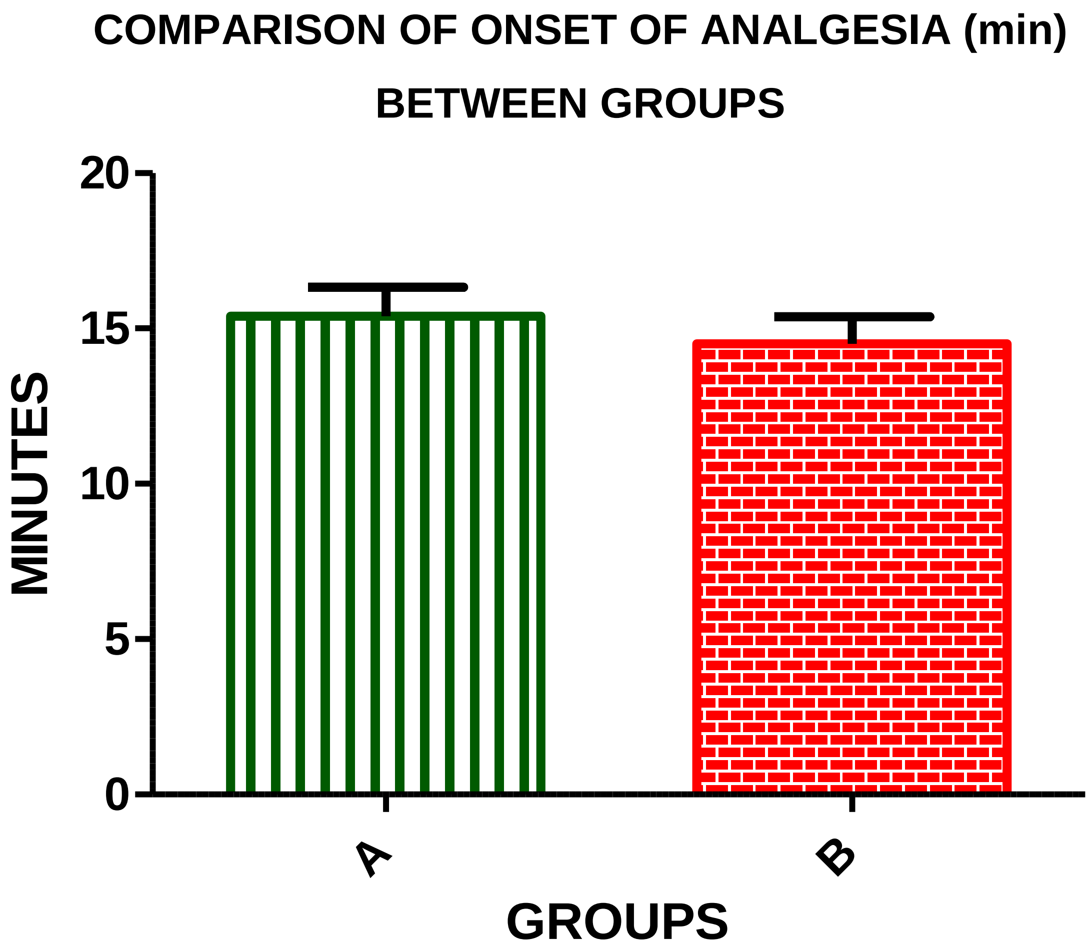


Figure: 8

As per Figure 8, Comparison of mean time of onset of analgesia (min) between the two groups (A and B). Error bar represents the standard error of mean (SEM). Unpaired t test was used to compare the two groups. There was no statistically significant difference between the groups ($p>0.05$)

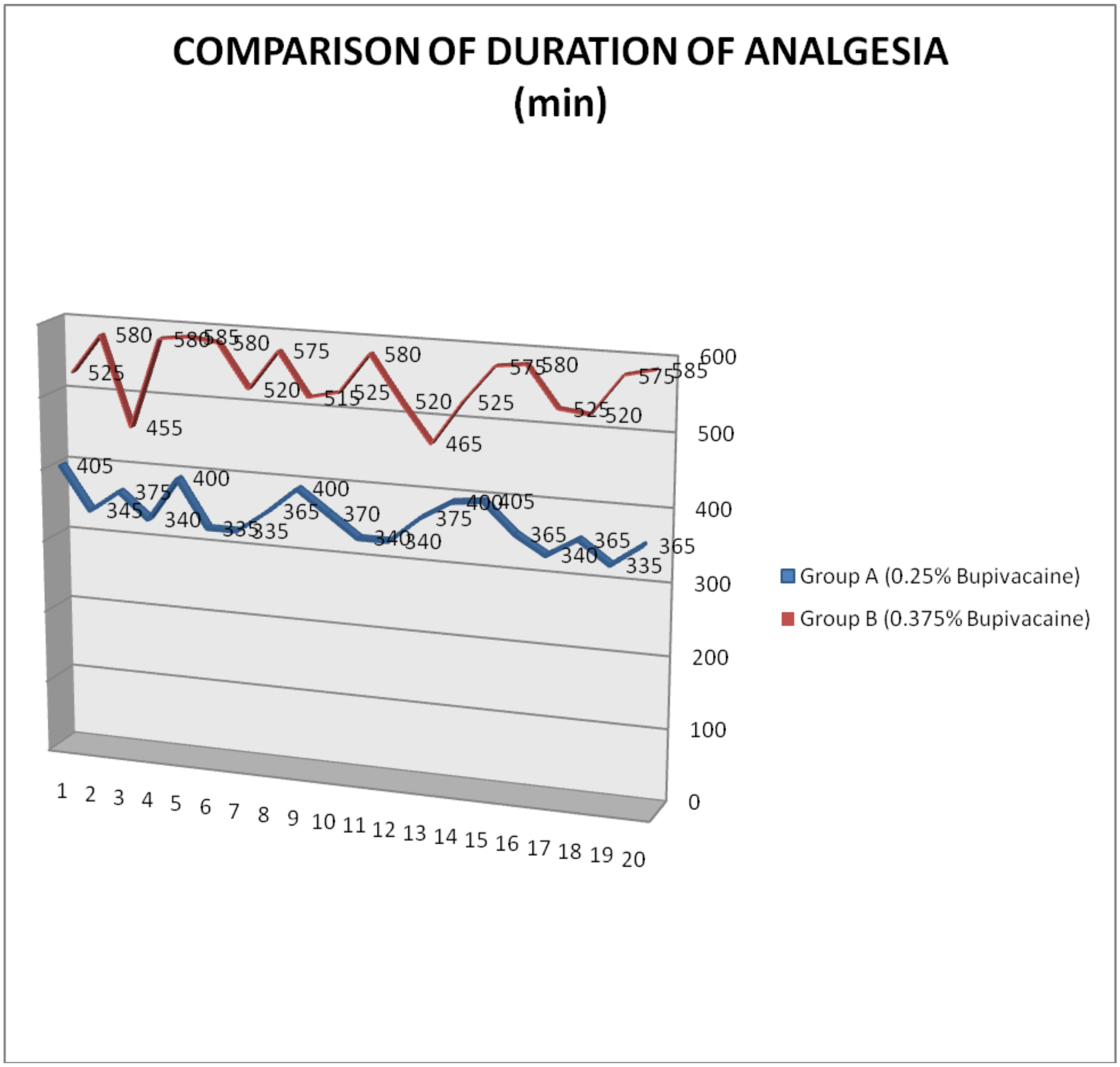

COMPARISON OF DURATION OF ANALGESIA
(min)
Group A (0.25% Bupivacaine)
Group B (0.375% Bupivacaine)
0
100
200
300
400
500
600
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

Figure 9:

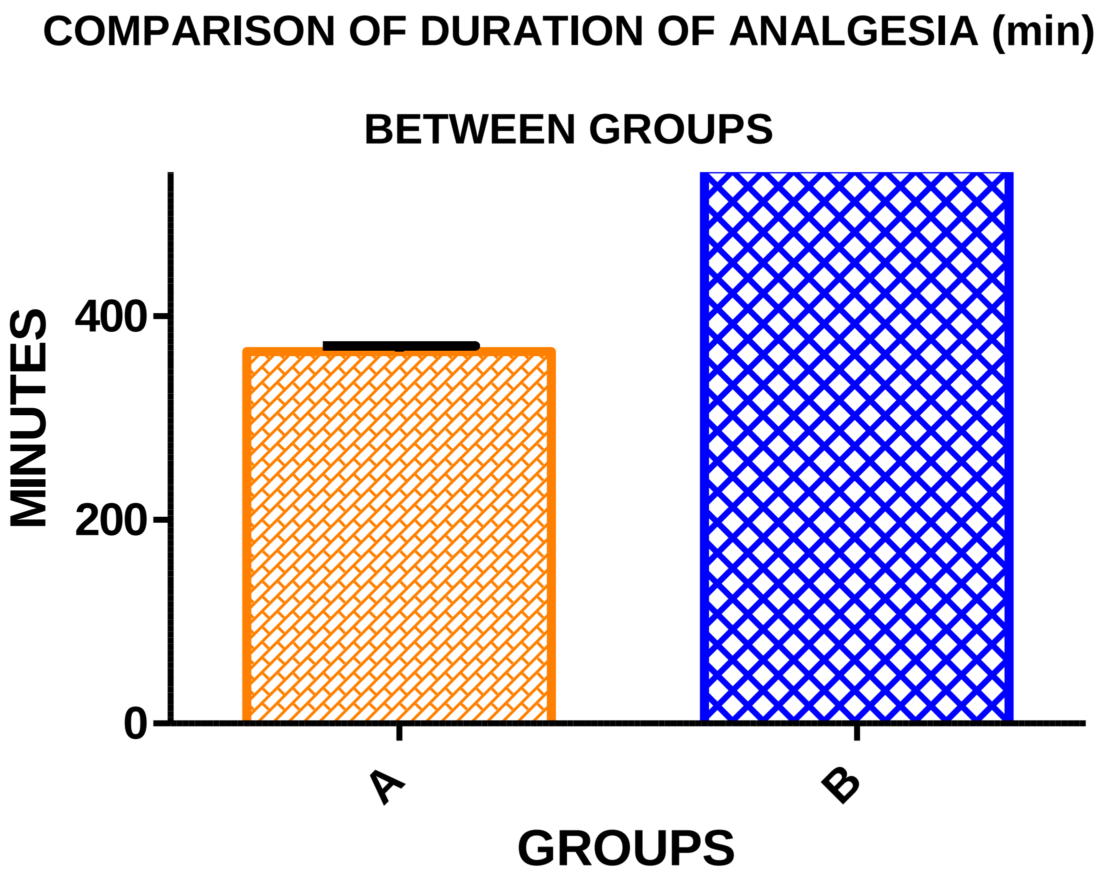


Figure: 10

As per Figure 9 & 10, Mean duration of analgesia (min) between the two groups (A and B) was compared. Error bar represents the standard error of mean (SEM). Unpaired t test was used to compare the two groups. The mean duration was significantly lower in the Group A compared to Group B ($p< 0.0001$)

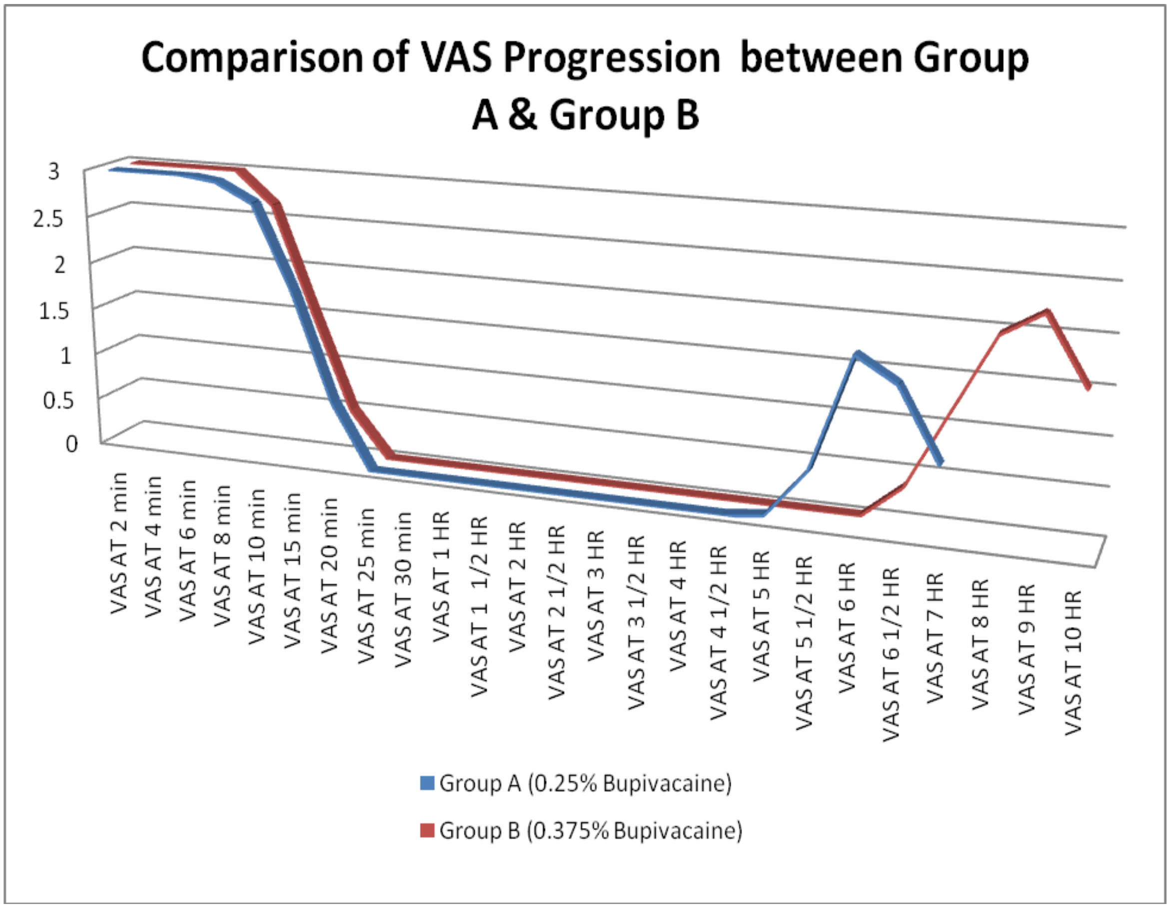


Figure: 11

As per Figure 11, Group B patients had lesser VAS score for prolonged duration compared to Group A

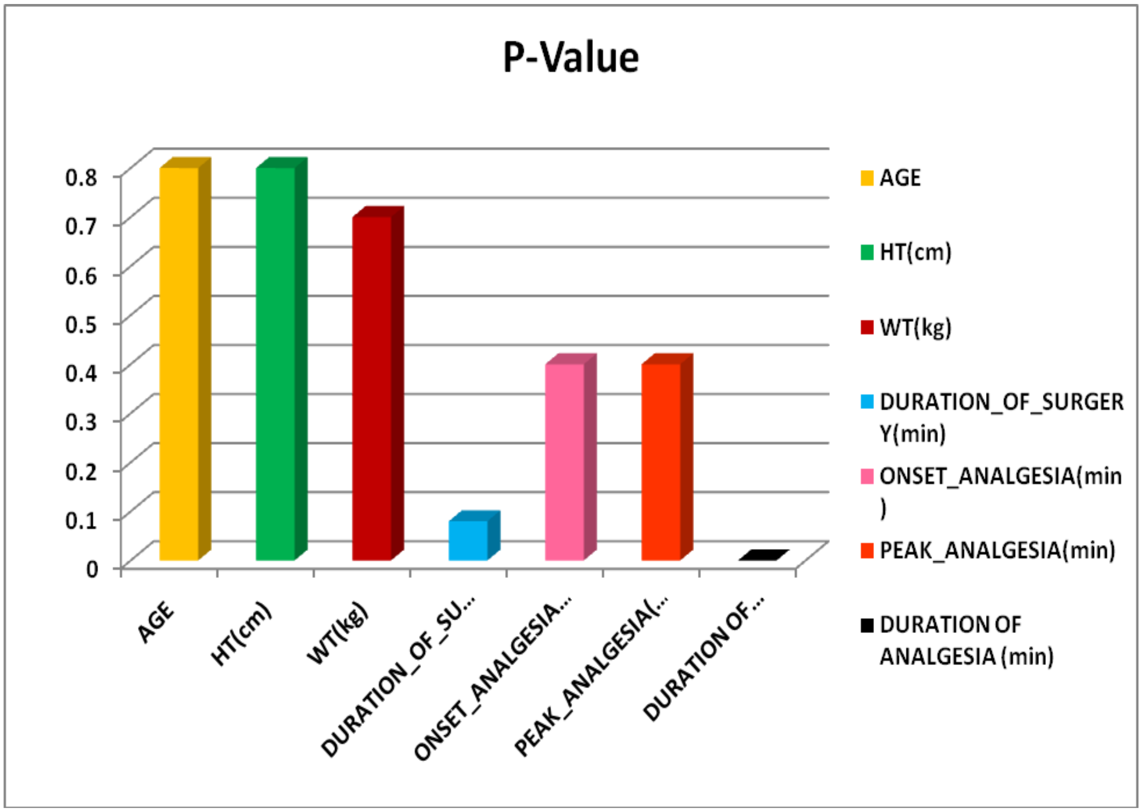


Figure: 12

As per the figure 12, statistically significant P-Value (<0.05) is obtained only for duration of analgesia which implies that 0.375% of Bupivacaine has prolonged duration of analgesia than 0.25%.

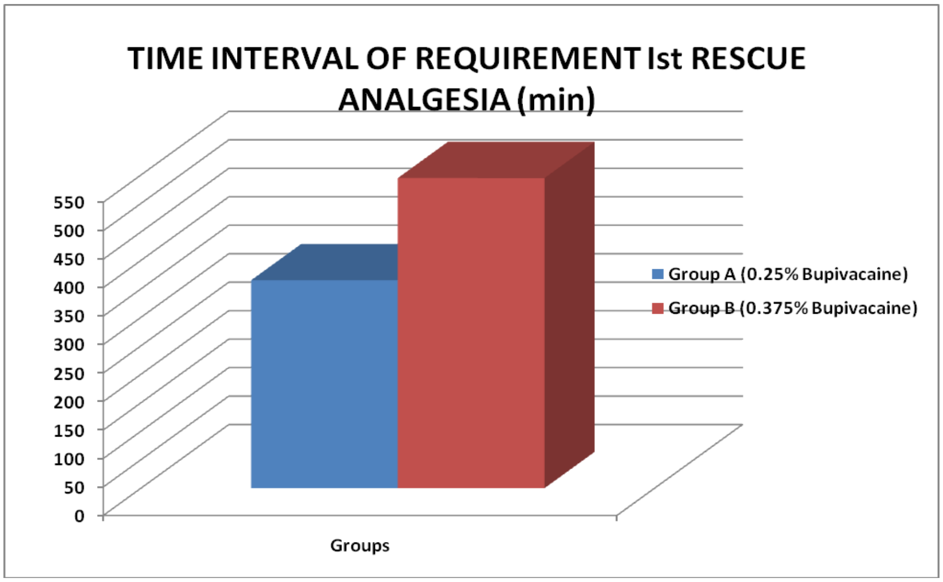


Figure: 13

As per Figure : 13, The First rescue analgesic dose required is earlier in Group A (0.25% Bupivacaine) than Group B (0.375% Bupivacaine)

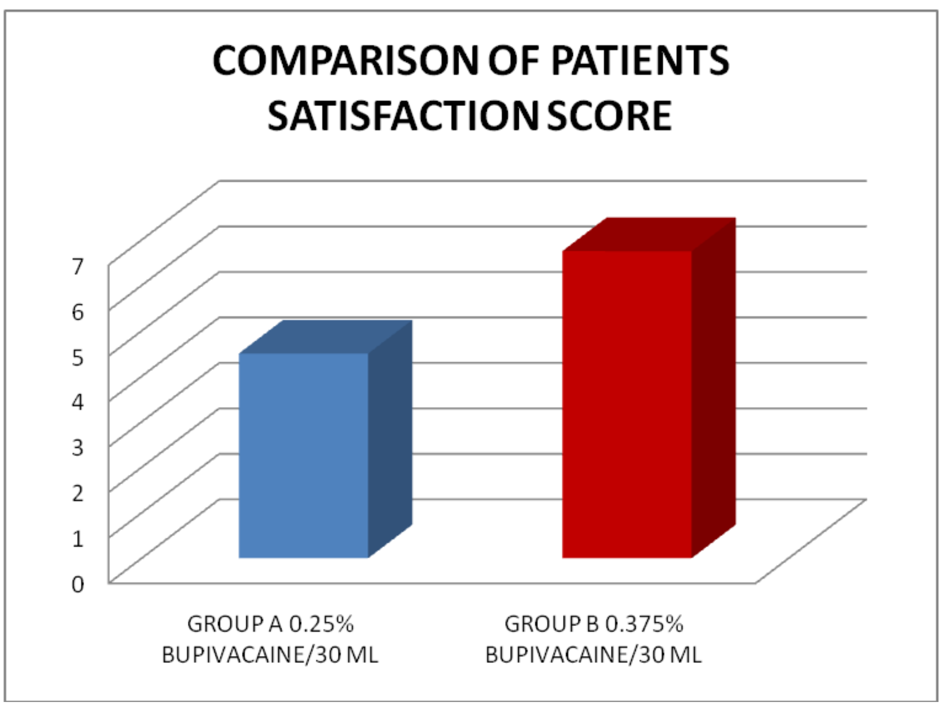


Figure: 14

As per Figure:14, Group B Patient had more satisfactory pain relief than Group A

13. DISCUSSION:

Based on the observation and results obtained in our study involving 20 patients in each group ,results of our study was discussed in detail by comparing with the obtained data and available evidence in the literature**.**

This study compared two different concentration of equivolume dose of bupivacaine in USG-TAP block in patients undergoing cesarean section via a pfannensteil incision. The patients selected in our study were patients undergoing cesarean section and these patients wants to be more alert and mobile in the immediate postoperative period for breast feeding and to care for their baby. Immediate pain relief in the post operative period has several implications in recovery of these patients. In our study the demographic profiles [as per table 1 and figure 1-4] like age, height, weight and BMI are comparable and there was no statistically significant difference between Group A and Group B.

There were no significant differences between the two groups regarding the ASA Physical status, surgery duration, surgeon and history of any previous abdominal surgery.

The effect of the USG-TAP block is more when the block is carried out in patients who are responsive and alert rather than in a sedated patient. In alert patient we are able to elicit the VAS pain score, the time of onset of analgesia and the intensity of pain relief can be very well studied.

In our study we used 0.25% and 0.375% bupivacaine for USG TAP block. We did not found any local anaesthetic toxicity in our study group.The volume and concentrations of LA are known in any studies and not much is known about onset time of analgesia and its duration. Therefore, it is necessary to study these parameters during a TAP block. In a recent study[29], done by Kato et al.,40ml was given in TAP block and serum concentrations of lidocaine was investigated .They found out that the serum concentrations were within the therapeutic range for the anti-arrhythmic effect of lidocaine. Hence it is suggested that the analgesic effect may be caused by a systemic rather than a local effect of the local anaesthetic, and needs further studies.

After initiation of the block, the time of Onset of analgesia was compared between the groups and it was noted that varying the concentration of local anaesthetic does not produce any significant difference in Onset of analgesia.

In our study, the VAS pain scores assessed in the US-TAP Block with 0.375% bupivacaine were significantly lower than the 0.25% group in the PACU in the immediate postoperative period. This demonstrates that the US-TAP block with higher concentration provides effective & prolonged analgesia in the initial postoperative stage. This study very well correlates with the study of ***Siddiqui et al.***[28] who in his analysis of Seven randomized, double-blinded studies of both blind and ultrasound guided TAP technique for postoperative analgesia in infra umbilical surgeries demonstrated average and significant reduction in IV PCA requirement as a part of multimodal analgesic regimen. He also demonstrated reduced VAS score both at rest and movement in the early postoperative period. He also found out there was reduced incidence of postoperative nausea, vomiting and sedation.

In our Study, the time interval for requirement of first dose of rescue analgesia was prolonged in 0.375% bupivacaine group[mean analgesic duration-544 min] than the 0.25%bupivacaine group[mean analgesic duration-365 min]. This finding suggest that the total rescue analgesic usage is decreased in the first 24–48 h among women who received a TAP block with higher concentration than the other, immediately after cesarean delivery. This correlates with studies of

PATEL et al., who found that there was a 34% reduction in oral narcotic dosing in patients who received a TAP block. They also observed decreased opioid usage and hence the decreased side effects of it like pruritus, vomiting and nausea. This block also facilitates early ambulation, no urinary retention, and a more active state of the patient.

In our study, there were no complications during the procedure or after the block. The adverse effects pertaining to the TAP block have been reported in the literature. There was a case report of liver trauma and peritonitis with US-TAP block in a patient who underwent hernioplasty. This incidence was due to failure to accurately image the entire needle while imaging, resulting in excessive penetration of the needle. Therefore, when the exact direction and depth of the needle is under real time images of the ultrasound, this complication can be avoided.

So far USG guided-TAP block has been used for very few surgical procedures only. But the USG guided -TAP block could be applied more widely, warranting further researches in this field. If this block is developed more, it can be used for treating the patient’s pain more effectively.

14. SUMMARY

A prospective randomized double blinded study was designed to compare the efficacy of 0.375% and 0.25% bupivacaine in ultrasound guided transversus abdominis plane block in patients undergoing elective lower segment ceaserean section under general anesthesia. Based on the analysis of the results and discussion in our study, the conclusions arrived at are summarized as below.

- There was no statistically significant difference in demographic profiles between the two studied groups.
- There was no statistically significant difference in Onset of analgesia between the two studied groups.
- The duration of analgesia was significantly prolonged with 0.375% Bupivacaine than 0.25%.[mean duration of analgesia – average of 365min with group A vs 544min with group B]
- Both the group of patients very well maintained their vital parameters throughout the study period.
- There was no failure of TAP block in either of the group and all patients had post operative pain relief for 6-10 hours.

- Patient satisfaction in all the patients in both the groups are good.
- There was no adverse reactions or side effects in either of the groups.
- There was no complications like local anaesthetic toxicity noted in both the groups.

15. CONCLUSION

Hence, we conclude that usage of 0.375% of Bupivacaine in USG guided TAP block significantly provide more prolonged duration of post operative pain relief after Elective LSCS compared to equivolume dose of 0.25% bupivacaine

We also conclude that 15 ML of 0.375% of Bupivacaine can be safely used in each side of TAP block for providing post operative pain relief after Elective LSCS without producing any adverse or toxic effects.

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17. ANNEXURES

PROFORMA

Name of patient :

Group assigned :

Age / Sex :

IP number :

Weight/ height :

Preop assessment

History-

Examination-

Airway assessment-

Diagnosis and indication for LSCS-

ASA status –

Last oral intake :

Premedication :

Duration of surgery :

Time of extubation :

Test solution number :

Time of Initiation of Block :

Onset of Analgesia :

Time of Requirement of First Rescue Analgesia:

Duration of Analgesia :

PATIENT CONSENT FORM

"A Study of Comparison of the efficacy of different concentration of bupivacaine in ultrasound-guided Transversus Abdominis Plane (TAP) block for postoperative pain relief in lower segment cesarean section"

Study centre: Department of Anaesthesiology & Critical Care, Kilpauk.

Medical college:

Participant name: Age: Sex:

I.P. no:

I, confirm that I have understood the purpose of procedure for the above study. I had the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfall in the procedure and the management of it. I have been explained about the safety, advantages and disadvantages of the techniques.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study.

I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

I hereby consent to participate in this study of "A Study to Compare the efficacy of different concentration of bupivacaine in ultrasound-guided transversus abdominis plane(tap)block for postoperative pain relief in lower segment cesarean section".

Name of the patient: Signature/thumb impression of patient:

Name of the witness: Signature:

Address: Contact Number:

Name of the investigator: Signature:

Time: Date:

Place:

MASTER CHART

GROUP A 0.25% BUPIVACAINE

S. NO.	NAME	AGE (Years)	HT (cm)	WT (kg)	INDICATION	ASA	DURATION OF SURGERY (min)	PAIN SCORE IMM. ATFER EXTUBATION	ALERGIC REACTION	POST OPERATIVE NAUSEA & VOMITING	POST OPERATIVE SEDATION
1	Neelaveni	21	164	54	Previous LSCS/CPD	II	50	3/10	0	0	0
2	Lakshmi Balakrishnan	26	164	58	Previous LSCS/CPD	II	45	3/10	0	0	0
3	Lakshmi Balasubramani	27	160	62	Previous LSCS/CPD	II	60	3/10	0	0	0
4	Ellammal	32	162	60	Previous LSCS/CPD	II	55	3/10	0	0	0
5	Sharma Devi	28	158	58	Previous LSCS/CPD	II	45	3/10	0	0	0
6	Sushila	27	166	68	CPD	II	50	3/10	0	0	0
7	Vengammal	25	160	56	Previous LSCS/CPD	II	55	3/10	0	0	0
8	Yamini	23	162	62	Prev LSCS	II	60	3/10	0	0	0
9	Poovarsi	28	158	58	Prev LSCS	I	45	3/10	0	0	0
10	Geetha	27	168	67	CPD	II	50	3/10	0	0	0
11	Kanniammal	24	162	65	Prev LSCS	II	55	3/10	0	0	0
12	Ponammal	26	158	57	Prev LSCS	I	50	3/10	0	0	0
13	Kalaiarsi	22	150	53	CPD	II	47	3/10	0	0	0
14	TamilSelvi	26	154	47	Prev LSCS	II	55	3/10	0	0	0
15	Sellammal	22	161	59	Prev LSCS	II	60	3/10	0	0	0
16	Parameswari	30	158	60	Prev LSCS	I	42	3/10	0	0	0
17	Sadhanya	27	165	60	CPD	II	46	3/10	0	0	0
18	Chitra	23	163	58	Prev LSCS	II	55	3/10	0	0	0
19	Rajini	30	153	56	Prev LSCS	II	50	3/10	0	0	0
20	Gomathi	25	151	50	Prev LSCS	II	55	3/10	0	0	0

GROUP A 0.25% BUPIVACAI

S. NO.	NAME	VAS AT 2 min	VAS AT 4 min	VAS AT 6 min	VAS AT 8 min	VAS AT 10 min	VAS AT 15 min	VAS AT 20 min	VAS AT 25 min	VAS AT 30 min	VAS AT 1 HR	VAS AT 1 1/2 HR	VAS AT 2 HR	VAS AT 2 1/2 HR	VAS AT 3 HR	VAS AT 3 1/2 HR	VAS AT 4 HR	VAS AT 4 1/2 HR	VAS AT 5 HR	VAS AT 5 1/2 HR	VAS AT 6 HR	VAS AT 6 1/2 HR	VAS AT 7 HR	VAS AT 8 HR	VAS AT 9 HR	VAS AT 10 HR
1	Neelaveni	**3**	3	3	2	2	0	0	**0**	0	0	0	0	0	0	0	0	0	0	0	1	1	3			
2	Lakshmi Balakrishnan	**3**	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	1	2	3					
3	Lakshmi Balasubramani	**3**	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	3				
4	Ellammal	**3**	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	1	3					
5	Sharma Devi	**3**	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	3			
6	Sushila	**3**	3	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	1	3					
7	Vengammal	**3**	3	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	2	3					
8	Yamini	**3**	3	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	1	3				
9	Poovarsi	**3**	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	3			
10	Geetha	**3**	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	1	3				
11	Kanniammal	**3**	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	1	3					
12	Ponammal	**3**	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	1	3					
13	Kalaiarsi	**3**	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	3				
14	TamilSelvi	**3**	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	3			
15	Sellammal	**3**	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	3			
16	Parameswari	**3**	3	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	1	3				
17	Sadhanya	**3**	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	2	3					
18	Chitra	**3**	3	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	2	3				
19	Rajini	**3**	3	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	1	3					
20	Gomathi	**3**	3	3	3	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	2	3				

GROUP A 0.25% BUPIVACAI

S. NO.	NAME	ONSET OF ANALGESIA (min)	PEAK ANALGESIA ONSET(min)	DURATION OF ANALGESIA (min)	PATIENT SATISFACTION VAS
1	Neelaveni	8	15	405	4
2	Lakshmi Balakrishnan	10	15	345	5
3	Lakshmi Balasubramani	10	15	375	5
4	Ellammal	15	20	340	4
5	Sharma Devi	15	20	400	4
6	Sushila	20	25	335	4
7	Vengammal	20	25	335	4
8	Yamini	20	25	365	4
9	Poovarsi	15	20	400	3
10	Geetha	15	20	370	5
11	Kanniammal	15	20	340	4
12	Ponammal	15	20	340	4
13	Kalaiarsi	10	15	375	4
14	TamilSelvi	15	20	400	5
15	Sellammal	10	15	405	4
16	Parameswari	20	25	365	4
17	Sadhanya	15	20	340	6
18	Chitra	20	25	365	5
19	Rajini	20	25	335	6
20	Gomathi	20	25	365	6